

**THE SALMONELLA OUTBREAK: THE ROLE OF
INDUSTRY IN PROTECTING THE NATION'S
FOOD SUPPLY**

HEARING
BEFORE THE
SUBCOMMITTEE ON OVERSIGHT AND
INVESTIGATIONS
OF THE
COMMITTEE ON ENERGY AND
COMMERCE
HOUSE OF REPRESENTATIVES
ONE HUNDRED ELEVENTH CONGRESS
FIRST SESSION

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THE SALMONELLA OUTBREAK: THE ROLE OF INDUSTRY IN PROTECTING THE NATION'S FOOD SUPPLY

THURSDAY, MARCH 19, 2009

HOUSE OF REPRESENTATIVES,
SUBCOMMITTEE ON OVERSIGHT AND INVESTIGATIONS,
COMMITTEE ON ENERGY AND COMMERCE,
Washington, DC.

The subcommittee met, pursuant to call, at 10:04 a.m., in room 2123, Rayburn House Office Building, Hon. Bart Stupak (chairman of the subcommittee) presiding.

Present: Representatives Stupak, Braley, DeGette, Schakowsky, Christensen, Sutton, Dingell (ex officio), Waxman (ex officio), Walden, Deal, Burgess, and Gingrey.

Also Present: Representative Schauer.

OPENING STATEMENT OF HON. BART STUPAK, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF MICHIGAN

Mr. STUPAK. This meeting will come to order. Today we have a hearing titled "The Salmonella Outbreak: The Role of Industry in Protecting the Nation's Food Supply." The Chairman, Ranking Member and the Chairman Emeritus will be recognized for a 5-minute opening statement. Other members of the subcommittee will be recognized for 3 minutes. I will begin.

As reports state, mold was observed growing on the ceiling and walls. Rainwater was observed dripping into the plant's peanut butter processing areas; six dead mice. Air filters were littered with feathers. A live roach and several dead roaches were observed in the firm's wash room. REPs, rodent extra pellets, were too numerous to count where observed.

The pictures you are seeing and the quotes I am reading come from Federal inspections of the facilities in Georgia and Texas, operated by the Peanut Corporation of America. At the subcommittee's first hearing on February 11, 2009, we heard testimony about filthy conditions and at least a dozen positive salmonella tests that PCA received in 2007 and 2008. Today the subcommittee will continue its investigation by hearing from representatives of three companies that bought products from these polluted PCA facilities, Kellogg Company, the King Nut Company and the Vitamin Cottage Natural Food Markets.

We will ask a series of questions today. First, we will ask why their food safety procedures failed to prevent the contamination of their products. The written testimony submitted for today's hearing

suggests that some of the companies believe PCA was entirely at fault, and that they should not be held responsible for the safety of ingredients they bought from a disreputable supplier. PCA certainly deserves its share of the blame, and there are ongoing criminal investigations of its actions, but all three of these companies put their own labels on these products. They put their names on them. They represented to the public that these products were safe to eat, and they sold them to consumers, who became ill and in some cases died. Placing all the blame on PCA would mean that food processors have no responsibility for ensuring the safety of their ingredients, and I simply can't agree with that. I cannot agree with that.

Second, we will ask whether these companies should have known or suspected problems with PCA before the outbreak. In written testimony submitted today, Martin Kanan, the president and CEO of King Nut, states that PCA's president Stewart Parnell informed King Nut on January 7, 2009, that he had no knowledge of any salmonella issues with his products. The documents tell a different story. On the same day, January 7, Mr. Parnell sent an e-mail to King Nut's vice president for finance and administration, Joe Valenza. In this e-mail PCA's president Mr. Parnell forwarded a news account of the emerging outbreak to King Nut's vice president and said, Joe, I am sure it is something we did. Eleven minutes later, King Nut vice president replied, I am recalling everything. Four minutes later Mr. Parnell replied, now my heart is really in my throat. I think I am going to church tonight.

Third, we will ask why none of these companies ever asked PCA officials to disclose their positive tests for salmonella. If your supplier tests positive, this is something definitely you should find out, and it is certainly something your customers deserve to know. Even industry insiders recognize this.

In an e-mail on February 5, 2009, an official at a private food safety auditing firm wrote to a coworker, the biggest problem was with the positive micro data that they ignored. This data was not initially available for the FDA either. They had to really pry into their documentation before uncovering the additional test results.

Fourth, we will ask why these companies relied on audits by AIB, a firm that was selected and paid by PCA. There is an obvious and inherent conflict of interest when an auditor works for the same supplier it is evaluating. And several documents show evidence of this cozy relationship. On December 22, 2008, PCA's auditor e-mailed Sammy Lightsey, the manager of PCA's Georgia plant, to give him advanced notice of an upcoming inspection. He stated, you lucky guy. I am your AIB auditor, so we need to get your plant set for any audit. The result of that audit was a superior rating. The conclusions were completely different when the auditors were not paid by PCA.

Today we will release several audits that have yet to be made public. They were concluded not by a PCA auditor hired by PCA, but by internal auditors working for Nestle USA. In 2002, Nestle auditors found that PCA's Georgia facility had no plan to address microbiological hazards like salmonella. Their audit found, quote, potential for microbiological cross-contamination, and concluded that PCA was not in compliance with housekeeping, sanitation and

pest control standards. The audit noted rodent droppings in the break room cabinets, live flour beetle in the blancher room, four dead beetles found in storage screens in the bleacher room, dead insects found on the interior perimeters. The audit warned that it is critical that these deficiencies are addressed, but its findings in 2002 were similar to the Federal investigation several years later.

Nestle USA also conducted an audit of Nestle's Texas in 2006 and came to similar results. As a result, Nestle USA rejected PCA as a supplier. We will ask the other companies here today, why did they not do the same? If they had, perhaps some of the illnesses and deaths would have been avoided.

In conclusion, I ask unanimous consent that the documents, my opening statement and the binder prepared by staff be entered into the official record. Without objection, so ordered.

[The information follows:]

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Energy & Commerce Committee
Oversight & Investigations Subcommittee
“The Salmonella Outbreak: The of Industry in Protecting the Nation’s Food Supply”
Opening Statement
Rep. Bart Stupak, Chairman
March 19, 2009

“Mold was observed growing on the ceiling and walls”...“rain water was observed dripping into the plant’s peanut processing areas”...“6 dead mice were found in the false ceiling area”...air filters were “littered with feathers”...“a live roach and several dead roaches were observed in the firm’s wash room”...“REPs [rodent excreta pellets] too numerous to count were observed.”

The pictures you are seeing, and the quotes I am reading, come from federal inspections of facilities in Georgia and Texas operated by the Peanut Corporation of America. At the Subcommittee’s first hearing on February 11, 2009, we heard testimony about filthy conditions and at least a dozen positive salmonella tests that PCA received in 2007 and 2008.

Today, the Subcommittee will continue its investigation by hearing from representatives of three companies that bought products from these polluted PCA facilities: the Kellogg Company, the King Nut Company, and Vitamin Cottage Natural Food Markets.

We will ask a series of questions today. First, we will ask why their food safety procedures failed to prevent the contamination of their products.

The written testimony submitted for today’s hearing suggests that some of the companies believe PCA was entirely at fault, and that they should not be held responsible for the safety of ingredients they bought from a disreputable supplier. PCA certainly deserves its share of the blame, and there are ongoing criminal investigations of its actions.

But all three of these companies put their own labels on these products. They put their names on them. They represented to the public that these products were safe to eat. And they sold them to consumers who became ill and in some cases died, according to state and federal authorities.

Placing all the blame on PCA would mean that food processors have no responsibility for ensuring the safety of their ingredients. And I simply can’t agree with that.

Second, we will ask whether these companies should have known or suspected problems with PCA before the outbreak. In written testimony submitted today, Martin Kanan, the President and CEO of King Nut, states that PCA’s president, Stewart Parnell, informed King Nut on January 7, 2009, that he had no knowledge of any salmonella issues with his products.

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The documents tell a different story. On the same day, January 7, Mr. Parnell sent an e-mail to King Nut's Vice President for Finance and Administration, Joe Valenza.

In this e-mail, PCA's president, Mr. Parnell, forwarded a news account of the emerging outbreak to King Nut's Vice President and said, "Joe, I'm sure it's something we did." Eleven minutes later, King Nut's Vice President replied: "I'm recalling everything." Four minutes later, Mr. Parnell replied: "Now my heart is really in my throat. I think I'm going to church tonight."

Third, we will ask why none of these companies ever asked PCA officials to disclose their positive tests for salmonella. If your supplier tests positive, this is definitely something you should find out, and it's certainly something your customers deserve to know.

Even industry insiders recognized this. In an e-mail on February 5, 2009, an official at a private food safety auditing firm wrote to a co-worker: "[T]he biggest problem was with the positive micro data that they ignored. ... this data was not initially available for the FDA either. They had to really pry into their documentation before uncovering the additional test results."

Fourth, we will ask why these companies relied on audits by AIB, a firm that was selected and paid by PCA. There is an obvious and inherent conflict of interest when an auditor works for the same supplier it is evaluating, and several documents show evidence of this cozy relationship.

On December 22, 2008, PCA's auditor e-mailed Sammy Lightsey, the manager of PCA's Georgia plant, to give him advance notice of an upcoming inspection. He stated: "You lucky guy. I am your AIB auditor. So we need to get your plant set up for any audit." The result of that audit was a rating of "superior."

The conclusions were completely different when the auditors were not paid by PCA. Today, we will release several audits that have not yet been made public. They were conducted not by the auditor PCA hired, but by internal auditors working for Nestle USA.

In 2002, Nestle auditors found that PCA's Georgia facility had no plan to address microbiological hazards like salmonella. Their audit found a "potential for microbiological cross contamination" and concluded that PCA was "not in compliance" with housekeeping, sanitation, and pest control standards. The audit noted:

- "Rodent droppings in the break room cabinets"
- "Live Flour beetle activity in the blancher room"
- "Dead Flour beetles found in stored screens in the bleacher room"
- "Dead insects found on the interior perimeters"

The audit warned that "it is critical that these deficiencies are addressed." But its findings in 2002 were similar to those of federal investigators seven years later.

Nestle USA also conducted an audit of PCA's Texas facility in 2006 and came to similar conclusions. As a result, Nestle USA rejected PCA as a supplier. We will ask the other companies here today why they did not do the same. If they had, perhaps some of these illnesses and deaths would have been avoided.

In conclusion, I ask unanimous consent that the documents in my opening statement and in the binder prepared by staff be entered into the official hearing record.

Mr. STUPAK. I next turn to my friend and colleague, Mr. Walden of Oregon, for an opening statement, please.

OPENING STATEMENT OF HON. GREG WALDEN, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF OREGON

Mr. WALDEN. Thank you very much, Chairman Stupak.

Since our last hearing of February 11, more facts have surfaced, and more people have been sickened by salmonella-contaminated products from the Peanut Corporation of America, including 13 cases in my home State of Oregon. The American public and the industries remain angry, they remain confused, and they are saddened by the outbreak and subsequent recall. This frustration is clearly understandable.

Now people want to assign blame. I want to go even further. Let us assign some blame and address the weak points in our food safety regulations that allowed this to happen. Let us make this the last time we have to have a hearing to examine what went wrong and finally fix the problems at hand.

The current reactive system of random samples has failed time and again, which brings to mind the famous saying by Albert Einstein, the definition of insanity is doing the same thing over and over again and expecting different results. We need to shift from the current reactive food safety system that depends heavily on product testing to a proactive and preventive strategy that relies on modern scientific standards and safety controls that detect and eliminate food-borne contamination as far up the chain as possible.

I bring to your attention H.R. 1332, the Safe FEAST Act, a bipartisan bill that has been introduced by our colleagues Congressman Jim Costa of California and Adam Putnam of Florida. It does just that. It is my understanding that a similar measure will be introduced in the Senate by Durbin and Gregg.

Our best chance for achieving our goal is for every participant in every step of the production, from the farm to the retail store, to take a hard look at the way they are doing things now and ask themselves, how can I improve? Then we need to hold their feet to the fire in implementing those improvements, farmers, retailers, the Food and Drug Administration, the State health service, and hospitals. The companies before us today who purchased products from PCA and private third-party firms who visited PCA and certified them each have a role in improving this process.

Peanut Corporation of America is an extreme case of bad actors who I believe recklessly endangered consumers, and the majority of the blame rests on their shoulders. PCA allegedly knowingly released contaminated product to consumers and companies, falsified test results and violated countless good manufacturing product practices. All of us are disgusted by the continuous horrid actions taken by the company.

Now, the food processors that I have spoken with in Oregon, some large, others smaller, have told me they do not produce or sell items that they would not feed their own children or their grandchildren. They have extensive vendor certification processes. They go through third-party audits, and each of them know it is in their company's best interest and their consumers', because without that,

it is impossible to stay in business. PCA did not operate by these standards.

I want to pull up a couple of pictures as well. On the screen are pictures taken of PCA's plant in Plainview, Texas, where contaminated products were produced and shipped into commerce. This is a picture—you really need to understand, this is the intake screen over the air that goes in to where the food has already been processed. Now, it is hard to really see clearly what is on this screen, but it doesn't take much imagination to believe there is at least one rotting rodent on that screen. These two pictures that follow are also of dead rodents. And what is especially disgusting is these are rodents that, again, are around the air intake that brought air in, in theory pure air, brought it in and put it over the processed product.

How does this go undetected in initial screenings? How do auditors go in and not spot this in the beginning? How did this company get a clean third-party audit? Something is wrong with the system. These are dead rodents and other contaminants that were present on and around PCA's air-handling equipment that, as I said, blows fresh air onto clean peanut products.

Media outlets report that this PCA plant had not been inspected by Texas health regulators or the FDA. That is because PCA violated the law by failing to register and apply for a food-manufacturing license from the State, another example of PCA's abhorrent behavior.

Hopefully the companies here today can help us understand what they do to ensure the quality and safety of their products and identify potential places for improvement. What are their supplier qualifications, and should more be required? What enhancements can be made? These three companies represent a variety of food manufacturers, including large establishment companies that have been in business for decades to small family-run companies that were all negatively impacted by PCA's recall.

We need your help in designing a process that works for the safety of food in America. The testimony today may be useful to enhance our legislative efforts, but the subcommittee should keep this case study in context because the deaths and illnesses from this outbreak were caused by one bad actor who clearly, in my opinion, violated the law. So the best way to protect young children, like 3-year-old Jake Hurley from my home State of Oregon, is to prevent it by stopping the bad apples like PCA, build in food safety measures at firms, and increase the strength of regulatory inspections by giving FDA access to all test results, especially those that are positive for contaminants during inspections, and expose and deter the bad actors.

Thank you, Mr. Chairman.

Mr. STUPAK. Thank you, Mr. Walden.

[The prepared statement of Mr. Walden follows:]

**Prepared opening statement of the Honorable Greg Walden
Ranking Member, Subcommittee on Oversight and Investigations
“Salmonella Outbreak: The Role of Industry in Protecting the
Nation’s Food Supply”
March 19, 2009**

Thank you Chairman Stupak. Since our last hearing on February 11, new facts have surfaced and more people have been sickened by salmonella contaminated products produced by Peanut Corporation of America, including 13 cases in my home state of Oregon. The American public and affected industries remain angry, confused and saddened by the outbreak and subsequent recall and this frustration is understandable. Now, people want to assign blame.

I want to go even further – let’s assign some blame AND address the weak points in our food safety regulations that allowed this to happen. Let’s make this the last time we have a hearing to examine what went wrong and finally fix the problems at hand.

The current reactive system of random sample testing has failed time and again. It brings to mind the famous saying: “The definition of insanity is doing the same thing over and over again and expecting different results.”

We need to shift from the current reactive food safety system that depends heavily on product testing to a proactive one that relies on modern scientific standards and safety controls that detect and eliminate food-borne contamination as far up the chain as possible. Testing is important, but it is not possible to test safety into food. H.R. 1332, the Safe FEAST Act, a bipartisan bill that has been introduced by our colleagues Jim Costa (CA) and Adam Putnam (FL) does just that. It is my understanding that a similar measure will be introduced in the near future by Senators Durbin and Gregg.

The best chance for achieving our goal is for every participant in every step of the food production and delivery process—from the farm to the retail store—to take a hard look at the way they are doing things now and ask themselves, “How can I improve?” Then we need to hold their feet to the fire in implementing those improvements. Farmers, retailers, the Food and Drug Administration (FDA), the state health departments, the companies like the ones here today who purchased product from PCA, and the private third-party audit firms like those that visited PCA and certified them each have a role in this process.

Peanut Corporation of America is an extreme case of bad actors recklessly endangering consumers, and the majority of the blame rests on their shoulders. PCA knowingly released contaminated product to consumers and companies, falsified test results, and violated countless Good Manufacturing Practices (GMPs). All of us are disgusted by the continuous abhorrent actions taken by the company.

But let's not throw the baby out with the bathwater. The food producers in Oregon that I contacted, some large others small, all told me that they do not produce or sell items that they wouldn't feed their own kids or grandkids. They have extensive vendor certification processes, go through third party audits and each of them know that it is in their companies' best interest to maintain the trust and loyalty of their customers because without that it is impossible to stay in business. PCA does not operate by these standards or principles.

On the screen are pictures taken at PCA's plant in Plainview, Texas where contaminated peanut products were produced and shipped into commerce. These pictures show dozens of dead rodents and other contaminants that were present on and around PCA's air handling equipment that blows onto fresh, clean peanut products.

Media outlets reported that this PCA plant had not been inspected by Texas health regulators or the FDA, that's because PCA violated the law by failing to register and apply for a food manufacturing license from the state. This is another example of PCA's abhorrent behavior.

Hopefully the companies here today can help us understand what they currently do to ensure the quality and safety of their products and identify potential places for improvement. What are their supplier qualifications and should more be required? What do their internal quality assurance programs look like and what enhancements can be made? These three companies represent a variety of food manufacturers, including large established companies that have been in business for decades to small family-run companies that were ALL negatively impacted by the PCA recall.

The testimony today may be useful to enhance our legislative efforts. But the subcommittee should keep this case study in context—the deaths and illnesses from this outbreak were caused by a bad actor. The best way to protect young children like 3-year old Jacob Hurley

from my home state of Oregon is to deter and or detect a bad actor as early as possible. The smart and most cost-effective way is to build in preventative food safety measures at firms, increase the strength of regulatory inspections by giving FDA access to all test results—especially those that are positive for contaminants—during inspections, and expose and deter bad actors.

Mr. STUPAK. Mr. Waxman for an opening statement, please, sir.

OPENING STATEMENT OF HON. HENRY A. WAXMAN, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF CALIFORNIA

Mr. WAXMAN. Thank you, Mr. Chairman. I want to commend you for the tenacious way that you have held hearings and tried to expose what is going on in the food safety area, especially the glaring holes at all levels of our food safety network.

This is the third hearing our committee has held in the committee of food safety. At our first hearing in February, it was clear that Peanut Corporation of America was more interested in its financial well-being than the health and safety of its customers. Rather than expressing regrets or sorrow for the illnesses the company caused, we saw internal communications where the company was more concerned about the fact they were losing money, more concerned about their financial bottom line.

At that hearing we also heard from the Food and Drug Administration about the authorities it lacks. The FDA doesn't even have the authority to routinely access records documenting the steps manufacturers take to assure safety. FDA can't even order a company to recall dangerous food products. It can only make a request and then hope the company complies.

Well, then in March we held our committee's second hearing before the Subcommittee on Health where the legislation will be considered. At that hearing witnesses explained that FDA cannot solve these critical problems alone. We rely on FDA, but there are over 300,000 registered food facilities throughout the U.S. and abroad, so we can't expect the FDA to prevent food-borne illnesses through inspections or post hoc investigations, so we rely on the companies. And today we are going to examine the role of industry in protecting our Nation's food supply.

We have got three companies that we are going to hear from today. They purchased peanut products from PCA despite the filthy conditions at PCA's plants in Georgia and Texas. These companies relied on PCA's review of the salmonella problem. They included them in their—they bought the products from PCA, and then they took these purchases and put it under their own label, and then they sold it to the public.

Well, when we heard from Dr. Stephen Sundlof, FDA's Director of Food Safety and Applied Nutrition, he said each company in the chain of manufacturing has an obligation to ensure that the ingredients they are using as well as their final products are safe for Americans to consume, and I wholeheartedly agree.

Nestle was going to buy products from PCA, but Nestle sent its own auditors out, their own inspectors, and they found that the place was filthy, and they realized that it was going to be a danger to their customers, so they didn't buy the products.

Kellogg realized that there may be a problem, but they insisted that PCA get its own inspection done, which PCA did by hiring a third-party auditor to inspect the facilities, and what they found was that under this third-party system, there was a for-profit auditing firm called AIB, and they gave PCA glowing reviews. This company was selected by PCA, it was paid by PCA, it reported to

PCA, and it realized that if they didn't give a good review, they weren't going to be hired again. So they did an audit, and then they gave PCA a certificate of achievement. Peanut Corporation of America was considered superior. That is what the auditors said about the Peanut Corporation of America. At the same time we have these horrible pictures of what was going on with rats and infestations in these plants.

Now, the question I think we want to know is how is it possible for a company that looks like this, with pictures of rodents, to receive an award like this where they are called superior? I think it raises a serious question of the flaw of these third-party inspections where there is a clear conflict of interest by the third-party inspector. And when you add to that what might be happening internationally, where foreign third parties are inspecting foods that we import into this country, it really has to make you think that there is something wrong, and we have got to clarify the situation. We have got to correct it.

Our goal now is to develop commonsense legislation to improve preventive services at the front end of this process before one more person dies from tainted food.

Thank you, Mr. Chairman.

Mr. STUPAK. Thank you, Mr. Chairman.

[The prepared statement of Mr. Waxman follows:]

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Opening Statement of Rep. Henry A. Waxman Chairman, Committee on Energy and Commerce

The Salmonella Outbreak: The Role of Industry in Protecting the Nation's Food Supply

Subcommittee on Oversight and Investigations

March 19, 2009

Thank you, Chairman Stupak. I want to commend you for your hard work on this investigation and for keeping the focus squarely where it belongs: on the glaring holes at all levels of our food safety network.

Today is the third hearing on these issues before the Energy and Commerce Committee. At our first hearing on February 11, it was clear that the Peanut Corporation of America was more interested in its financial well-being than the health and safety of its customers.

Rather than expressions of regret or sorrow for the illnesses the company caused, we saw internal communications complaining about the impact that positive *salmonella* tests were having on the company's bottom line.

We also received testimony from FDA about basic authorities it currently lacks. FDA does not have the authority to routinely access records documenting the steps manufacturers take to assure safety. FDA cannot order a company to recall dangerous food products — it can only make a request and hope the company complies.

On March 11, we held our Committee's second hearing, before the Subcommittee on Health. At that hearing, witnesses explained that FDA cannot solve these critical problems alone. There are over 300,000 registered food facilities throughout the U.S. and abroad, and we cannot expect FDA to prevent food borne illness through inspections or post hoc investigations.

Today we will examine the role of industry in protecting our nation's food supply. We will hear from three companies that purchased peanut products from PCA, despite the filthy conditions at its plants in Georgia and Texas.

These companies used PCA ingredients that were tainted with *salmonella*. They included

them in their own products under their own labels, and they caused illnesses and in some cases even death, according to state and federal officials.

At our February hearing, Dr. Stephen Sundlof, FDA's Director of Food Safety and Applied Nutrition, agreed that "each company in the chain of manufacturing has an obligation to ensure that the ingredients they are using as well as their final products are safe for Americans to consume."

I wholeheartedly agree. But, as we will see today, all three companies failed to meet this standard. Their final products were not safe, and people suffered as a result.

Let me make one final point. Some of today's witnesses, and many companies like them, relied on third party auditors to inspect the facilities of their suppliers. This hearing will expose some of the dangers related to this system. I raised serious concerns about this at our hearing last week.

If we are going to consider a third party system, we must, at minimum, ensure it addresses the serious problems we will hear about today. But there are additional problems this hearing won't address, such as using foreign third parties to inspect foods we import from other countries. This Committee will be looking closely at all of these issues in the coming weeks.

In this case, a private, for-profit auditing firm called AIB gave PCA glowing reviews. This company was selected by PCA, it was paid by PCA, and it reported to PCA.

Let me show you an award it gave to PCA on August 20, 2008. This "certificate of achievement" was given to PCA's Texas plant for fulfilling "the requirements of the AIB Consolidated Standards for Food Safety."

And you can see the "superior" rating between the signatures of AIB's President and the Chairman of the Board.

We've all now seen the pictures of what this Texas plant was really like: rodents, excrement, and filth.

How could a facility that was in such deplorable conditions receive such glowing reviews?

And how is it possible that any of our witnesses could have relied on such flawed inspections?

We will have hard questions for our witnesses today, but we also thank them for their cooperation. They provided thousands of pages of documents to the Committee, and they helped state and federal authorities remove deadly products from family kitchens across the country.

Our goal now is to develop common sense legislation to improve preventive systems at the front end of this process before one more person dies from tainted food.

Mr. STUPAK. Mr. Deal from Georgia, opening statement, 3 minutes, please.

OPENING STATEMENT OF HON. NATHAN DEAL, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF GEORGIA

Mr. DEAL. Thank you, Mr. Chairman. Thank you for holding the hearing. Thanks to our witnesses for being here.

Obviously all of us, regardless of which side of the aisle we sit on, are very concerned about keeping the food supply of this country safe. That is a function that I see has already been stated is a dual function. First of all, it is primarily preventive in nature. We must try to make sure that nothing contaminates that food supply and, if at all possible, to prevent it. And that, too, is a bifurcated function. It is the function of private industry, those who produce, those who process and those who distribute; and then there is a function of the Federal Government, and that is, more or less, oversight of all of those functions.

The panel's makeup today obviously will focus on the industry side of the agenda, and there is some important questions I think we all need to ask, and that is, what should we legislatively require in terms of prevention that we are not doing currently? For example, should there be certification of independent third-party auditors? Should there be certification of independent labs? Should there be mandatory testing of product; and if so, how often and at what stage of the processes? Should those reports from those tests be made available to inspectors, both FDA, USDA and third-party inspectors, when they come to look at the facilities that are involved?

These are all questions that are legitimate, but I think we all understand that a lot can be done on the private side of the ledger, and perhaps more should be done on the government side. I hope today's testimony will allow us to make some interaction between those two separate private and governmental functions so we know and have direction as to how we should approach this issue.

Thank you, Mr. Chairman.

Mr. STUPAK. Thank you, Mr. Deal.

Mr. Dingell for an opening statement, please.

OPENING STATEMENT OF HON. JOHN D. DINGELL, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF MICHIGAN

Mr. DINGELL. Thank you, Mr. Chairman. I commend you for holding this hearing, and for your long-standing effort to fix Food and Drug so that they can do their job the way it should be done.

We have been working on this in this committee for several years. As you will recall, last Congress you, Mr. Chairman, and I spent considerable time trying to get—the story of Food and Drug's incompetence, inability to carry out its responsibility, lack of resources, and general overall indifference to its responsibility at the leadership levels was a source of considerable interest by this subcommittee.

I would note that we are now talking about dreadful lapses in accountability by State and Federal authorities as well as members of the industry in ensuring the safety of the Nation's food supply.

This is not a new thing. We had the grapes. We had the jalapeno peppers and tomatoes. We had a severe problem with imported Chinese seafood and shellfish. We have had terrific problems with imported heparin, and now we have got the peanuts. And you, Mr. Chairman, and I have found reason to be highly critical of Food and Drug for lack of resources and for the basic statute which has not really been changed since 1962.

As I made clear then in the subcommittee's previous hearings, this is not a new problem. Nine hearings were held by this subcommittee in the prior Congress, and we questioned the system designed to protect Americans from dangerous foods and drugs, and how it was not working, and how Food and Drug did not have the resources, at a cost of 1,600 or 1,700 people, killing 9, costing our State of Michigan nearly \$1 million to combat, depriving businesses of revenues due to recalls. And I note that other businesses have been hurt by this as well as American consumers, who unfortunately have been killed and sickened.

And I would note that the most recent outbreak of salmonella is clearly a result of deplorably unsanitary conditions at the Peanut Corporation of America's Georgia and Texas plants, and it clearly illustrates that the need for overhaul of our system for protecting the Nation's food and drug supply is long overdue.

And I would note that when Georgia—well, first of all, Food and Drug never got in to look at the place, but finally Georgia went in after 8 years of inaction by FDA under delegated authority from FDA, and they couldn't find a thing. Apparently nobody in that business of inspection can find anything, including the seat of their pants with two hands.

In any event, last month's hearing dealt with federal and State regulatory faults that contributed to the peanut butter-related salmonella outbreak. What concerns us today is the role of industry in protecting the health and safety of consumers. Nestle, for example, refused to contract PCA as a supplier due to the fact that in its own due diligence it found unsanitary conditions at PCA's processing facilities. Georgia Food and Drug couldn't and didn't.

All the same, I understand that diligence is not uniform across the industry. I intend to ask our witnesses frank questions about their operational protocols ensuring safety of the products supplied to them for the final process. It might be noted that they are showing an extraordinary level of trust in a system and an agency that do not work. I wish to learn what best practices they have in place for protecting consumer health and safety, as well as if they monitor the sanitary conditions at their suppliers' processing facilities. Finally, I would like to ask the witnesses assembled here today if they support increased and strengthened authorities for Food and Drug, and adequate resources and funding, and whether they are willing to pay a registration charge to see to it that Food and Drug has the funds and the resources which this skinflint Congress has never given them.

Mr. Chairman, you, Chairman Pallone and I have introduced H.R. 759, the Food and Drug Administration Globalization Act of 2009, which will guarantee a reliable stream of sources through registration fees on food manufacturers to support increased inspection of foreign and domestic processing plants by FDA. This

bill is predicated on the notion that FDA must be strengthened not by replacing it with some new questionable food safety agency, bringing new layers of bureaucracy into the system, and whether that will come at too great a cost for the taxpayers.

It is my hope that the witnesses today will recognize the urgency of enacting H.R. 759 and offer their support. It is a sensible bill. It will protect American consumers from farm to fork.

Thank you, Mr. Chairman. I yield back the balance of my time.

Mr. STUPAK. Thank you, Mr. Dingell.

Mr. Burgess for an opening statement, please. Three minutes.

**OPENING STATEMENT OF HON. MICHAEL C. BURGESS, A
REPRESENTATIVE IN CONGRESS FROM THE STATE OF TEXAS**

Mr. BURGESS. Thank you, Mr. Chairman. I appreciate the witnesses being here today.

This is so important that we get this right going forward because, as Mr. Dingell already pointed out, we have had hearing after hearing after hearing, and we have done nothing about the problem. It is time for us to move on this, and it is also so important to get the policy right, because we see that if we get the policy wrong, people lose lives, not to mention the amount of dollars we lost in the recent problem.

The aftermath of this recent outbreak of salmonella are still being felt. I think your sales have dramatically decreased, and the recalls are still being issued. None of us are satisfied with the lack of answers from the Peanut Corporation of America at our hearing earlier in February.

We hold this hearing now to determine how the industry should move forward. And the problems are not just with the industry. Most companies want to maintain the integrity of their product and their trust and the relationship they have with the American people, the American consumer. And they have in place good manufacturing procedures. But when that trust is broken by bad actors like the Peanut Corporation of America, controls must be in place to swiftly address and correct the problem.

And I am not an expert on food safety, but this is not microbiological rocket science. You heat the peanuts up to a temperature that is high enough to kill the bugs for long enough, and if your plant isn't just in violation of every code, your product is going to be OK. It is so easy, it doesn't require anything exotic like radiation or some new procedure. It is as old as peanut preparation has always been. It is not that hard to do. That is why it just defies logic and defies gravity that PCA wouldn't take the necessary steps.

The logical path forward; how should Congress address this food safety legislation? Well, currently the Food and Drug Administration, in my opinion, is missing three logical controls that would allow them to effectively, efficiently and expeditiously clamp down on food-borne illness, and the first is access to records. Currently the Food and Drug Administration has no power to get the full records of a company. Instead, the Federal agency is like children requesting from a parent to have something of which they may not be entitled. The Food and Drug Administration has to politely ask

the company for a position that defies logic when food safety—when a food safety crisis is in place.

The Food and Drug Administration should not have to ask permission to go in for those records. They should be given the power to obtain those records.

Second, we have got to modernize the traceability of the system through greater use of electronics. Now, we in the medical profession are routinely excoriated for the slowness with which we adopt electronic medical records. FDA testified more than 95 percent of their records are on paper, so when there is a food-related problem, the staff at the Food and Drug Administration is digging through boxes and boxes in some warehouse to find out who did what to whom when. These should be converted to an easily navigable electronic database.

Also, companies should use the hazard access critical control points. The Food and Drug Administration currently requires juice companies and poultry companies to use this system, so it seems like—all meat and poultry companies to use this system, so it seems like it would be logical to require all domestic food products to do so as well.

Third, the Food and Drug Administration should have the power of mandatory recalls. If a company does not voluntarily pull their product, and they have been identified to contain food-borne illnesses, the Food and Drug Administration should have the power to mandatorily recall its product. Unfortunately, with food safety, when questions arise, the product is guilty unless proven innocent, and that is the legacy that we are going to be left with because of bad actors in the business.

Mr. Chairman, thank you. I will yield back the balance of my time.

Mr. STUPAK. Thank you.

Ms. DeGette for an opening statement please, 3 minutes.

OPENING STATEMENT OF HON. DIANA DEGETTE, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF COLORADO

Ms. DEGETTE. Thank you very much, Mr. Chairman.

We have had a series of hearings. I think this is about the thirteenth now. I am always sorry to be here because what that means is we haven't solved the problem yet. This salmonella with Peanut Corporation of America situation reminded me of a case I studied in law school. It is all there. All things are present here. We need to have the third-party inspections. We need to have the mandatory record provision. We need to have mandatory recall authority, and we need to have traceability. And all of these companies who are here today will talk to us about how having bad suppliers, having bad actors can affect all of the food industry.

I particularly want to welcome Ms. Isely here today from Colorado and for Vitamin Cottage, a well-known business that I have known for years, ever since I was a young girl growing up in Denver. I think Vitamin Cottage is a good example of sort of the collateral damage that can happen when you have bad actors in the food system, because this is a small, family-run, organic foods grocer which gets its food and its provisions from a lot of different suppliers. It is all good to say that it is their responsibility at Vitamin

Cottage to inspect all of the people that provide them food, but in truth it is virtually impossible for a small business to do that. And in this case—I will be interested to hear Ms. Isely talk about this—is they actually received assurances from Peanut Corporation of America that these peanuts were being produced in a healthful way. And frankly, if you are a small natural foods grocer, the last thing that you want to do is be making people sick, because that is going to affect your ability to do business, and it is going to affect your bottom line.

And so instead, I think what we need to look at in this committee is how we can ensure that the whole food chain, the whole food supply chain, is safe. That means the things that I talked about a few minutes ago, and that everybody on both sides of the aisle in this committee are talking about.

And finally I will say, I think that the Vitamin Cottage experience is a good example of how traceability can actually work well, because once these patients were identified by the Colorado Department of Health as having been sickened by salmonella, we were able to trace rather quickly back to where these peanuts came from. And so I think that if we could institute traceability throughout the whole system, we may well have identified this problem much sooner. We may have been able to recall the peanuts much sooner. Many hundreds—fewer people would have been sickened, and we might even have been able to save some lives.

So I am eager to hear from our witnesses, too. I think they will add a very valuable perspective into putting all the puzzle pieces together to solve this broken system.

Mr. STUPAK. Thank you.

Mr. Gingrey, opening statement, please, sir.

OPENING STATEMENT OF HON. PHIL GINGREY, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF GEORGIA

Dr. GINGREY. Mr. Chairman, thank you.

I want to say to Mr. Kanan and Ms. Isely that I agree with Congresswoman DeGette with regard to the collateral damage. I want to admit also that I am a physician Member almost addicted to peanut butter, and also am at the age where I have to take a number of medications on a regular basis. And let me assure you, when it says don't take on an empty stomach, with a little bit of peanut butter, the medicine goes down in the most delightful way. And that is what I generally do with a number of my pills and capsules. Now I have to worry about whether or not salmonella is going down with them, which is a shame.

And, of course, we are talking about one very bad actor whose headquarters is not in Georgia, but certainly the plant was in Georgia.

There is no question but that the safety of the American people is first and foremost the responsibility of government at every level, from providing for our national defense, indeed to protecting our Nation's food supply.

Our responsibility today is to get to the bottom of this most recent salmonella outbreak, knowing that what we learn will inform the legislative work not just of this subcommittee, but the other subcommittees and the full committee. However, we must all, I

think, keep in perspective that we live in a world of almost infinite needs, but definitely finite resources. Of course, I am talking about money. We also should not lose sight that at the core of this particular outbreak is an individual company, PCA, and ownership that acted, in my opinion, criminally.

As I stated at the last oversight hearing, regardless of how high a regulatory wall we erect, there is always going to be someone brazen enough or stupid enough or greedy enough to try to climb over it. So let us remember that we should also review the penalties for folks who knowingly, knowingly, circumvent our food safety system.

Mr. Chairman, with that, I will yield back.

Mr. STUPAK. Thank you.

Mr. Braley for an opening statement, please.

**OPENING STATEMENT OF HON. BRUCE L. BRALEY, A
REPRESENTATIVE IN CONGRESS FROM THE STATE OF IOWA**

Mr. BRALEY. Thank you, Mr. Chairman and Ranking Member, for this hearing.

Last year I spent a lot of time in my district visiting elementary schools, sitting in, about the importance of food safety. And if you have any doubt about the importance of this hearing today, I would urge you all to go visit an elementary school in your district during lunchtime and sit down and talk to kids about what impact food safety has on their lives.

This hearing is particularly timely for me because as a Member of Congress from Iowa, at least 27 confirmed cases of salmonella traced to alfalfa sprouts have been identified in my State in the recent weeks. The infected sprouts were sold by an Omaha company to food distributors in Iowa and Nebraska, and further sold the product to grocery stores and restaurants. And while the outbreak of salmonella linked to PCA peanuts has received much more attention on a national basis because of the sheer number of illnesses and products recalled, this more recent outbreak, which has led to 70 confirmed salmonella outbreaks in 4 States, provides evidence that the PCA salmonella outbreak was not just an isolated incident, and reminds us all of the urgency of fixing our food safety system.

This outbreak in Iowa also emphasizes something that was abundantly clear at last month's hearing. We need to enact comprehensive reforms to our food safety system that will necessarily encompass the entire food industry. As you all know, we heard troubling testimony about the unsanitary and unsafe conditions at PCA last month, and that led to hundreds of illnesses and as many as nine deaths nationwide. We also learned about the failure of the FDA in State investigations to identify problems at PCA and about the FDA's limited remedies under current law. That is why this hearing is so important.

As Ms. DeGette pointed out, we are going to keep visiting this subject until we get it right and until there is no longer a need to hold these repeated follow-up hearings. And that is why I want to thank the Chairman and Ranking Member for their interest in getting this information out to the public in such a timely manner.

And I yield back the balance of my time.

Mr. STUPAK. Thank you, Mr. Braley.
Ms. Sutton, please, for an opening statement.

**OPENING STATEMENT OF HON. BETTY SUTTON, A
REPRESENTATIVE IN CONGRESS FROM THE STATE OF OHIO**

Ms. SUTTON. Thank you, Mr. Chairman. And thank you for holding the second hearing on the salmonella outbreak and FDA oversight.

At the last hearing it became very, very apparent that the safety of our food supply is not as it should be. The salmonella outbreak that originated from Peanut Corporation of America has taken a disproportionate toll on Ohio. I have mentioned it before. But since October 2008, Ohio has reported 100 cases, including 2 deaths, due to salmonella. This is far more than any other State. What is perhaps even more alarming is that there are still cases being reported.

I would like to draw your attention to a news article from March 13 titled "Salmonella Cases: Half Still Come from Crackers. Recalled Food Continues to Sicken Consumers." The article states that nearly 2 months after the initial recall, and despite massive publicity, Federal health officials are still worried that some consumers have not gotten the message. There are families who keep peanut butter crackers in their cupboards and may not realize that they were recalled; worse yet, reports that some stores have not pulled the contaminated products from their shelves.

The bottom line, Mr. Chairman, even though these products were recalled, the execution of the recall was flawed. That is why it is so important for Congress to fix our food safety system, and I applaud your willingness to take on this task.

Currently the FDA lacks the authority to issue mandatory recalls of tainted products. Furthermore, the FDA does not require proof that recalled products have been destroyed. I introduced the Protect Consumers Act, which gives the FDA mandatory recall authority. I also support other legislation sponsored by many in this committee that call for better reporting for contaminated products and tracing products once they are recalled.

I am interested in hearing from our panel today that represents companies affected by the outbreak. I am especially eager to hear from Mr. Kanan and from King Nut Company, which is in northeast Ohio. And, Mr. Chairman, I look forward to working with you and all of our colleagues to fix our broken food inspection system.

And I yield back.

Mr. STUPAK. Thank you.

Ms. Schakowsky, opening statement, please.

**OPENING STATEMENT OF HON. JANICE D. SCHAKOWSKY, A
REPRESENTATIVE IN CONGRESS FROM THE STATE OF ILLINOIS**

Ms. SCHAKOWSKY. Thank you, Mr. Chairman, for this important hearing. Ensuring food safety is a critical issue for this committee and Congress, and I am happy we are moving forward on this legislation.

I began my career as a consumer product safety advocate as a very young housewife in Illinois—I won't give you the year—who

just wanted to pick something off a grocery shelf and know how long it had been sitting there, a day, a week and a year. And along with a small group of other similarly minded young housewives, and with a tremendous amount of perseverance, we succeeded in getting freshness dates on food packages. There was never any regulation, but the freshness dating, which is now ubiquitous, began to roll like a snowball. We never thought another label would be needed, "salmonella free."

This is the second hearing we have had by the Subcommittee on Oversight and Investigations linked to the Peanut Corporation of America. According to the Illinois Department of Health, to date 10 individuals in my State have been made ill by that strain of salmonella. As of March 1, CDC has documented 67 illnesses nationwide with 1 in 4 people hospitalized, and you know about the deaths. This outbreak has disproportionately affected the young, a population even more likely than adults to consume peanut butter and peanut butter products. Half of those made sick were children under the age of 16, and 1 in 5 were children under the age of 5.

In February, we heard testimony from Peter Hurley, whose young son was made ill from eating Austin Peanut Butter Crackers. Those crackers were made by the Kellogg Company using peanut paste sold by Peanut Corporation of America. I, along with many others, was shocked with documents presented in the February hearing that showed that PCA knew that their products were tainted, and yet released them into the food supply anyway. This recklessness and negligence have caused the deaths of nine people.

There are many places where the system broke down. One, the Peanut Corporation of America was not required to report to anyone, not the FDA, not the companies buying their peanuts, when their products tested positive for salmonella. Two, the private companies that audited PCA were not subject to uniform standards or apparently strong enough standards as the FDA found many violations not reported in the private company's earlier audits. Three, the FDA had to use its authority under the Bioterrorism Act just to gain access to PCA's files showing their product had tested positive for salmonella.

We can and we must do better than that. And I hope today's hearing and testimony from companies that purchased products from PCA will help us identify how we can improve our food safety system.

Thank you, Mr. Chairman. I yield back.

Mr. STUPAK. Thank you.

That concludes the opening statements by all members of the subcommittee.

I should point out Mr. Schauer is here from Michigan. He has talked to the Members individually throughout the course of this.

You have Kellogg's in your district, right?

Mr. SCHAUER. Yes.

Mr. STUPAK. Mr. LaTourette, who I thought would be stopping by, but I know he is talking to a number of people in his office, he has got a number of people sick in his district, and King Nut is in his district; and, of course, Ms. DeGette has Vitamin Cottage Natural Food Markets. I would not be surprised to see other Members

coming back and forth. There are other hearings and other panels going on. I will recognize them as they come in.

Let us call our first panel of witnesses to the table. I would like to welcome these witnesses and thank them for testifying today. I want to make one thing clear: While your companies are those that have been directly linked to the illnesses, that CDC acknowledges that their products, your products, do not explain all of the illnesses associated with the salmonella outbreak. There are many other companies that purchased products from PCA and have contributed to the salmonella outbreak. These companies have been cooperative, have voluntarily come forward and have worked with the CDC, FDA and others to try to get our hands around this salmonella outbreak, the largest food outbreak of food-borne illness in our country.

So I would like to welcome our panel. First we have Mr. Martin Kanan, who is president and chief executive officer of the King Nut Company based in Ohio. We have Mr. David Mackay, who is the chief executive officer of the Kellogg Company based in Michigan. We have Ms. Heather Isely, who is the co-owner of the Vitamin Cottage Natural Food Markets, Incorporated, based in Colorado. I welcome you all.

It is the policy of this subcommittee to take our testimony under oath. Please be advised that under the rules of the House, you have the right to have and be advised by counsel during your testimony. Do any of you wish to have counsel with you and wish to be advised by counsel during your testimony?

Mr. Kanan, would you just identify who they are for the record?

Mr. KANAN. I have Valoria Hoover and Anne Corrigan.

Mr. STUPAK. OK. Mr. Mackay.

Mr. MACKAY. I have Charles Sklarsky.

Mr. STUPAK. Ms. Isely.

Ms. ISELY. I have with me Mr. Barnette from Steptoe & Johnson.

Mr. STUPAK. During testimony if you want to consult with them or be advised by them, that is great, but you would be the one who would answer questions.

I will ask you to rise and please raise your right hand to take the oath.

[Witnesses sworn.]

Mr. STUPAK. OK. Let the record reflect the witnesses have replied in the affirmative. They are now under oath.

We will hear a 5-minute opening statement. We have your longer statements you have submitted for the record. I and others, I am sure, of the committee have read your opening statements. So if you want to give us 5 minutes, please, we would appreciate it.

Mr. Kanan, let us start with you.

TESTIMONY OF MARTIN KANAN, PRESIDENT AND CHIEF EXECUTIVE OFFICER, KING NUT COMPANY; DAVID MACKAY, CHIEF EXECUTIVE OFFICER, KELLOGG COMPANY; AND HEATHER ISELY, CO-OWNER, VITAMIN COTTAGE NATURAL FOOD MARKETS, INC.

TESTIMONY OF MARTIN KANAN

Mr. KANAN. Good morning, Mr. Chairman and members of the subcommittee. My name is Martin Kanan, and I am the president and CEO of Kanan Enterprises, better known as King Nut. We are a family-owned and -operated business and are a leading national supplier of snack nuts and other snack foods.

Let me begin by saying something you have heard many times: The health and safety of those who consume our products is our first priority. Kanan has always reviewed its processes to identify lessons learned. Such continuous improvement is how we grew from 25 employees in 1989 to almost 200 today. Our union-run facilities by the Teamsters produce nearly 500 million bags of products per year, none of which is associated with this outbreak.

We began selling peanut butter because our customers asked us for it; however, we are not a peanut butter manufacturer. In early 2004, PCA started as King Nut's private labeler of peanut butter. This means they supplied us finished product in a sealed container, packed by them, with our label put on it by them, in a closed and finished case. Throughout the 5 years of doing business with PCA, we received spec sheets for their products, highlighting that no salmonella be present. We also received several continuing pure food guarantees that stated any product shipped to us would be unadulterated, safe and free from any substance which would harm the consumer. They also gave us certificates of assurance; a total quality systems audit summary report; a letter from Stewart Parnell, PCA's president, extolling a superior rating from AIB; and assurances that PCA had a HACCP plan in place. Late in the relationship we received COAs that showed negative results for salmonella.

By the end of 2008, we distributed the PCA peanut butter to seven food service distributors. We did not suspect any health issues existed with the PCA product until we were contacted by the Minnesota Department of Agriculture. We were the very first in the United States to do the voluntary recall for any product associated with this salmonella outbreak.

On Wednesday, January 7, we received a call from the MDA informing us they were investigating the salmonella incidents. They wanted to know who manufactured the King Nut peanut butter. We told them it was PCA. When we contacted PCA, Stewart Parnell, their president, informed us he had no knowledge of a salmonella issue.

On the next day, FDA investigators came to our facilities. We produced bills of lading and COAs from PCA. We asked the FDA to take samples of the peanut butter to test, but they declined. Therefore, on the same day we sent samples ourselves of the lots of peanut butter we had in house to be tested. Also on the same day we received a second call from the MDA informing us that the peanut butter was a possible suspect, and that samples from an open container had been sent out for testing.

The next day, Friday, January 9, the FDA investigators again returned to our facility. We informed them we did not use any peanut butter in any of the products we manufactured. Several hours later the FDA investigators then took samples of the peanut butter we had for testing. At 4:30 that Friday afternoon, we received news from the MDA that sampling from the open container of peanut butter had a presumptive positive for salmonella, and that the subtype would not be confirmed until the following week.

Now, even though it was a single container, and even though it was only a presumptive positive, we decided to do the recall. We did not want to wait for PCA. Our biggest concern was for the health and safety of our customers. So prior to noon that Saturday, January 10, over the weekend, we initiated the first product recall associated with the salmonella outbreak. We recalled all of the PCA peanut butter that King Nut distributed in 2008. All of our seven food service distributors were aware of the recall that same afternoon. That day we also issued a nationwide press release as we did not know who might be the ultimate customer or consumer.

On Monday, January 12, the FDA investigators again came to gather more information. We were also called and informed that 4 of the 13 samples from that opened container had tested positive for salmonella typhimurium. That confirmed that our quick reaction to the presumptive positive was the right thing to do.

Three days after we initiated the recall, PCA did it. As this subcommittee is aware, PCA's recall has been expanded many times. We, along with those in our industry and the consumers, were shocked and dismayed at findings that PCA knowingly released product with potential salmonella contamination into the food supply.

The test results from our January 8 in-house samples were negative. To this day FDA has not told us the results of those January 9 samples they took from our warehouse.

Now, while I believe that the American food supply is one of the safest in the world, Kanan Enterprises continues to be committed to working at rebuilding public confidence in the American food safety system. I want to be a part of making things better for our country's food supply.

In this specific case of PCA, I must reiterate that we did not have control over the production nor the processing of this product. While most food manufacturers practice safe production, storage and handling of food ingredients, it is apparent that if someone lacks the integrity and honesty, they will always be able to find ways to bypass any quality assurance or food safety program.

We need to let the American public know that we have better systems in place to react quickly to correct our problems and punish the wrongdoer. This is a tragedy for all of those involved, the victims, the families, our industry.

I thank you for this opportunity to discuss these issues with you, and I am happy to answer any questions you have.

Mr. STUPAK. Thank you.

[The statement of Mr. Kanan follows:]

PREPARED STATEMENT OF

J. MARTIN KANAN

PRESIDENT and CEO

KANAN ENTERPRISES, INC.

SOLON, OHIO

BEFORE THE

**SUBCOMMITTEE ON OVERSIGHT AND
INVESTIGATIONS**

COMMITTEE ON ENERGY AND COMMERCE

U.S. HOUSE OF REPRESENTATIVES

WASHINGTON, D.C.

MARCH 19, 2009

INTRODUCTION

Good morning Mr. Chairman and members of the Subcommittee. My name is Martin Kanan and I am President and CEO of Kanan Enterprises, Inc. Since 1989, Kanan Enterprises, my family owned business, has done business as King Nut Company. We are proud that the operating companies that my family now owns started in 1927 and 1937 in Cleveland, Ohio. We are a leading national supplier of snack nuts and other items to airline, retail, vending, food service, gift and private label industries.

I understand that today's hearing is to investigate the safety of the nation's food supply and specifically to examine the recent *Salmonella* outbreak associated with peanut products manufactured by the Peanut Corporation of America (PCA). Let me begin by stating something that you've heard many times before from others in the food industry, and will hopefully hear many times in the future: The health and safety of those who consume our products is our first priority. Food safety is paramount.

That is why Kanan Enterprises has always and will always regularly review and analyze its processes, procedures, plans and actions to identify lessons learned and areas for improvement. Such continuous improvement is how Kanan Enterprises grew from 25 employees in 1989 to almost 200 today. Our union run facilities, by the proud Teamsters Union, produce nearly 500 million bags of product per year. None of which is associated with this outbreak. With the growth in volume of product, we also grew in our sophistication on other aspects of the business. However, we have never lost sight and we will never lose sight that the key to longevity is producing safe, wholesome, quality food items.

The recent Salmonella outbreak is a tragedy for all of the victims, their families and the food industry. Thus, I will share with this subcommittee our relationship with Peanut Corporation of America and our role in being the first to recall PCA's peanut butter.

RELATIONSHIP WITH PEANUT CORPORATION OF AMERICA

As our business expanded, our foodservice customers began asking us if we would supply them with peanut butter. Our customers wanted industrial sized peanut butter, 5 lb and 35 lb containers. However, we are not a peanut butter manufacturer. To help us find a peanut butter manufacturer, we enlisted one of our long standing peanut brokers and asked that our broker find a peanut butter manufacturer that would "private label" the finished product for us. Private labeling for us meant that the manufacturer would sell us a high quality, finished, sealed product packaged with our label in a closed and finished case. Kanan would not manufacture, process or package the peanut butter.

Our first supplier of peanut butter had issues meeting a good consistency in the product, so our customers asked us to change. In early 2004, our peanut broker then presented PCA to us. In the peanut products industry, PCA is very well known and PCA had supplied, among others, a world leading food manufacturer. In 2004, PCA started as King Nut's private labeler. Over the years,

PCA private labeled King Nut's 5 lb creamy and crunchy peanut butter. Kanan also purchased from PCA, Parnell's Pride which is a 35 lb creamy peanut butter.

Throughout the 5 years of doing business with PCA, we received PCA's specification sheets for the products. The specification required, among many other microbiological requirements, no *Salmonella* to be present in the product, which we understood would be confirmed by testing. We've learned that contamination of peanut butter with *Salmonella* is usually an issue of recontamination after the roasting process. Such contamination would normally be dealt with through the application of GMP measures including sanitation and separation of finished product from raw materials.

In addition to product specification sheets, we received several Continuing Pure Food Guarantees from PCA. These Guarantees affirmatively stated that PCA guaranteed that any product shipped by PCA to Kanan was produced in accordance with good manufacturing practices, was unadulterated, safe and free of any substance which was in any way injurious. These Continuing Pure Food Guarantees were backed up by certificates of insurance, a Total Quality Systems Audit Report Summary, a letter from Stewart Parnell, PCA's President, extolling a Superior Rating from A.I.B. (American Institute of Baking) and assurances that PCA had a HACCP food safety plan in place. Late in the relationship, we received Certificates of Analysis or COA's. These COA's showed negative results for *Salmonella*.

At the end of 2008, Kanan distributed the PCA-manufactured and packaged peanut butter to seven foodservice distributors. Kanan never opened or altered the sealed containers of peanut butter. We did not suspect any health, safety or quality issues existed with PCA product until we were contacted on January 7, 2009, by the Minnesota Department of Agriculture.

RECALL

We were the first in the United States to do a voluntary recall for any product associated with the recent *Salmonella* outbreak. The timeline on the recall began with a call from the Minnesota Department of Agriculture. On Wednesday, January 7, 2009, they informed us that they were investigating *Salmonella* incidents and wanted to know who manufactured the King Nut peanut butter. We told them that it was PCA. We contacted the broker for PCA and requested that PCA be informed of the investigation into the product. In response, Stewart Parnell, President of PCA, let us know that he had no knowledge of any *Salmonella* issue.

On Thursday, January 8, 2009, FDA investigators came to our facilities and stated they were in the early stages of investigation. We produced the bills of lading and the COA's from PCA for the peanut butter and they inventoried the lots of peanut butter we had in our warehouse. At that time we requested the FDA take samples of the peanut butter to test, but they declined to take test samples. Therefore, on that same day, we sent samples of the lots of peanut butter that we had in our warehouse to be tested for salmonella. On January 8, 2009, we also received a second call from the Minnesota Department of Agriculture informing us that peanut butter was a possible suspect and that samples from an open container had been sent for testing.

On Friday, January 9, 2009, the FDA investigators returned to our facility and we again answered questions regarding who manufactured the peanut butter. We informed them that we did not use peanut butter in any of the products we manufactured. Several hours later, the FDA investigators took samples of the peanut butter in our warehouse for testing.

At 4:30 pm on Friday, January 9, 2009, we received news from the Minnesota Department of Agriculture that the sampling from the open container of peanut butter had a presumptive positive for *Salmonella* and that the sub-type would not be confirmed until the following week. Even though it was a single open container and even though it was only a presumptive positive, my company took this very seriously. We wanted to protect the public. We did not want to wait for PCA to initiate a recall.

Prior to noon on Saturday, January 10, 2009, we initiated the first product recall related to the *Salmonella* outbreak. We recalled all of the PCA peanut butter that King Nut distributed in 2008, both King Nut and Parnell's Pride labels. Again, even though we were only a distributor, we did the recall without PCA as we believed it was the right thing to do. Our biggest concern was for the health and safety of the consumers of the products.

Under our recall system, we are able to communicate with our customers within approximately 45 minutes. All of our customers, the 7 foodservice distributors, were aware of the recall by the afternoon of January 10. On January 10, 2009, we also issued a nationwide press release as we did not know who might be the ultimate end consumer of the product.

On Monday, January 12, 2009, FDA investigators again came to gather more information about the recalled peanut butter and we provided them with all records they requested. We were also called and informed that 4 of the 13 samples from the open container of peanut butter in Minnesota had tested positive for *Salmonella* Typhimurium. This confirmed that our quick reaction to the presumptive positive was the right thing to do.

On January 13, 2009, PCA initiated a voluntary recall of certain lots of peanut butter and peanut paste produced on or after July 1, 2008, due to the risk of *Salmonella* contamination. As this Subcommittee is aware, PCA's recall has been expanded several times.

On January 29, 2009, we along with those in our industry and the consumers were shocked and dismayed at the findings that reported PCA knowingly released product with potential *Salmonella* contamination into the food supply.

The test results from our January 8 samples showed no *Salmonella* in the product. To this day, we have not been informed by the FDA or anyone else what the test results showed from the samples the FDA investigators took on January 9 from our warehouse.

RECOMMENDATIONS

The issue of food safety and the questions concerning the breakdowns in the food safety system have brought into question whether America's food supply is safe. This question is much broader than the recent *Salmonella* outbreak associated with PCA's peanut products. While I believe that the American food supply is one of the safest in the world, Kanan Enterprises continues to be committed to work to rebuild public confidence in the American food safety system, including both governmental oversight and manufacturing accountability. I want the food safety system to work and I want to be part of making things better for our country's food supply.

In the specific case of PCA, however, Kanan Enterprises must reiterate that it did not have control over the production or processing of the product, PCA did. PCA had guaranteed Kanan that its peanut butter would not have *Salmonella*. While most food manufacturers practice safe production, storage and handling of food ingredients, it is apparent that if someone lacks integrity and honesty they will be able to find ways to bypass any quality control or food safety system. I believe any system created by Congress will necessarily have to keep the public confidence by showing that even if something does go terribly wrong, the system reacts to correct it swiftly and punishes the wrong doer.

Food manufacturers bear the responsibility of safe food. As a responsible food manufacturer. I abide by the rules and expect all to abide by the rules.

CONCLUSION

This is a tragedy for all those involved - the victims, their families and our industry. Even though we would not have wanted to be thrown into this spotlight, I thank you for the opportunity to discuss these issues with you and would be happy to answer any question that you have.

Mr. STUPAK. Mr. Mackay, your opening statement, please.

STATEMENT OF DAVID MACKAY

Mr. MACKAY. Good morning, Mr. Chairman and members of the subcommittee. I am David Mackay, president and CEO of the Kellogg Company. We sell our products here and in more than 180 countries and employ more than 32,000 people.

First and foremost, we deeply regret that the recent salmonella recall situation occurred and that it involved Kellogg products. We apologize to our customers and consumers, especially those who have become ill from one of our products.

We, just like members of this subcommittee, Federal and State regulators, medical professionals, and the general public, are deeply disturbed by the events we have learned of over the past few months with respect to Peanut Corporation of America.

We thank the subcommittee for the opportunity to discuss these important issues, in particular, how we can work together to strengthen the safety of the U.S. food supply.

PCA has essentially poisoned the well for an industry in which most companies are honest and trustworthy and pride themselves on delivering safe, wholesome products that consumers expect and deserve. The PCA situation has shown that, if a company chooses to ignore even basic food safety principles, food safety systems and protections can be compromised.

One of our governing values is to have the humility and hunger to learn. With that focus, our food safety program operates on the principle that food safety is a process of continuous improvement. And, in that spirit and as a result of what we have learned from this unfortunate situation, we have taken several immediate actions to enhance our food safety efforts.

We have established new Kellogg cross-functional teams, including quality, food safety, and engineering groups, to audit supplies of high-risk ingredients, and have completed these on-site audits of our peanut and peanut paste ingredient suppliers. We are also requiring these suppliers to conduct environmental testing and monitoring in their plants, which we believe from our own practices is pivotal in identifying, assessing, and correcting potential contamination before it becomes a major food safety problem. And we are strengthening our internal food safety training and education across our supply chain.

In the U.S. food safety system, we believe the key to enhancement is a renewed focus on prevention so that potential sources of contamination are identified and properly addressed before they become actual food safety problems. My written statement outlines our recommendations. However, I would like to provide highlights of our proposals.

We support the following nine industry and government enhancements: one, establish a single food safety authority under Health and Human Services, supported by a food safety advisory council, to strengthen and maximize the efficiency of regulatory oversight; two, establish an international food protection training institute to train government and industry inspectors; three, improve current good manufacturing practices, or GMPs, which have not been updated for over 22 years; four, develop food safety plans for every

food facility that are based on a thorough risk assessment and contain verification systems and preventative controls; five, require annual FDA inspections of facilities that produce high-risk foods; six, require test results and corrective actions to be disclosed to FDA at their annual inspection; seven, develop consistent food manufacturing audit standards and accredit auditors and the audit firms; eight, provide FDA with mandatory recall authority to expedite necessary recalls; and finally, nine, review possibilities for enhancing traceability standards.

Kellogg is firmly committed to working together with Congress, industry, and other stakeholders to evaluate and advance these recommendations. I look forward to discussing them with you today, and I want to thank you on behalf of the company and our employees for this opportunity to discuss these important issues. I am happy to answer any questions you may have.

[The prepared statement of Mr. Mackay follows.]

**Statement of A. D. David Mackay, President & Chief Executive Officer
Kellogg Company
Hearing on “The Salmonella Outbreak: The Role of Industry in Protecting the
Nation’s Food Supply”
United States House of Representatives, Committee on Energy & Commerce
Subcommittee on Oversight and Investigations
10:00 a.m. Thursday, March 19, 2009
2123 Rayburn House Office Building**

Introduction

Good Morning Mr. Chairman and members of the Subcommittee. I am David Mackay, President and CEO of the Kellogg Company. Kellogg is the world's leading producer of cereal and a leading producer of convenience foods, including cookies, crackers, toaster pastries, cereal bars, fruit snacks, frozen waffles and veggie foods. The company's brands include *Kellogg's*®, *Keebler*®, *Pop-Tarts*®, *Eggo*®, *Cheez-It*®, *Nutri-Grain*®, *Special K*®, *Bear Naked*®, *Kashi*®, *Rice Krispies*®, *Murray*®, *Austin*®, *Morningstar Farms*®, *Famous Amos*®, *Carr's*®, *Plantation*® and *Ready Crust*®. Our company began with 44 employees in Battle Creek, Michigan in 1906. Today we employ more than 32,000 people and sell our products in more than 180 countries around the world.

Kellogg has been bringing our best to consumers for more than 100 years. We have a longstanding commitment to upholding the highest quality in our operations. It is what our consumers and customers expect and what we strive to deliver.

First and foremost, we deeply regret that the recent Salmonella recall situation occurred and that it involved Kellogg's products. We apologize to our customers and consumers, especially to those who may have become ill from one of our products.

We, just like members of this Subcommittee, federal and state regulators, medical professionals and the general public, are deeply disturbed by the events we have learned of over the past two months with respect to Peanut Corporation of America (PCA).

These events have had a very significant impact on our consumers and our Company, and we regret any role our products may have played in the Salmonella outbreak. We thank the Subcommittee for the opportunity to discuss these important issues, in particular, how we can work together to strengthen the safety of the U.S. food supply.

PCA's Business with Kellogg

PCA's Blakely, Georgia facility was one of our suppliers of peanut paste, that we used in our Cary, North Carolina bakery to manufacture *Austin*® and *Keebler*® brand peanut butter sandwich crackers. PCA also supplied ingredients to other companies that manufacture certain limited product lines for Kellogg. We received our first shipment of peanut paste from PCA in July, 2007.

Consistent with Kellogg protocol, we qualified PCA to do business through our multi-step qualification process prior to receiving shipments from them. The initial step in this qualification process is requiring that PCA provide us with an independent, third-party food safety audit report. It is common industry practice to rely on third-party audits to supplement a company's own requirements for suppliers.

PCA provided us with an independent audit report prepared for them in 2006 by American Institute of Baking International (AIB). AIB is one of several audit firms commonly relied on in the food industry. The report gave PCA an "Excellent" rating and noted some minor improvements needed. We requested information from PCA to verify that the improvements were made. PCA provided us with written certification that corrective actions had been taken.

At the same time, we required PCA to complete a risk analysis assessment, which we refer to as our Raw Material Information Sheet (RMIS). This requires a supplier to provide comprehensive information on a variety of factors, including documentation of safety plans (such as Hazard Analysis and Critical Control Point (HACCP)), allergen controls, microbiological parameters and test methodologies). This tool serves as the foundation for our ongoing monitoring of a supplier.

Another step in the process requires suppliers to represent in writing in the form of a "Certificate of Analysis" that an independent lab has confirmed that the ingredient supplied has, among other things, tested negative for pathogens, including *Salmonella*.

As part of our ongoing supplier monitoring, Kellogg also requires qualified suppliers to provide annual independent, audits of their facilities. PCA retained AIB to conduct food safety audits in 2007 and 2008 of their Blakely, Georgia facility. AIB audited core areas of food safety including: "Adequacy of Food Safety Program," "Pest Control," "Operational Methods and Personnel Practices," "Maintenance for Food Safety" and "Cleaning Practices."

Audit findings reported no concerns that the facility may have had any pathogen-related issues or any potential contamination. In fact, each report provided that PCA had formalized programs in place, including a HACCP program, as well as a program for the control of bacteria that included sending environmental samples to outside laboratories for testing. In addition, the reports referenced the results of the plant's most recent regulatory inspections where no, or only a few minor, issues had been found. None of the *Salmonella* or hygiene issues that have been reported by regulators over the past several months were noted in any of the audit reports provided to Kellogg.

Kellogg's Response

On January 12, 2009, PCA advised our Cary facility of an issue with specific peanut butter lots produced in their Blakely, Georgia facility. Kellogg purchased only peanut paste, not peanut butter, from that facility.

On January 13th, the Food & Drug Administration (FDA) notified us that Kellogg's *Austin*® peanut butter sandwich crackers may be implicated in PCA's *Salmonella* problems. We requested information about the specific products, lot dates and Universal Product Codes, and information on whether tested products were open or unopened. Unfortunately, FDA was unable to provide these details.

Despite having very limited information about a possible implication for our products, we immediately activated our Corporate Incident Management Team, a multidisciplinary team that investigates, among other issues, significant quality and food safety issues. The team commenced an internal investigation including reviewing our own environmental pathogen testing results at our Cary facility (the location where peanut butter sandwich crackers are produced), which were all negative for *Salmonella*. We also reviewed the Certificates of Analysis that PCA had provided Kellogg for each lot of paste received, and they were also all negative for *Salmonella*. Despite our findings, and out of an abundance of caution, we shut the lines down that day at our Cary facility and put product shipments on hold.

On January 14, 2009, per Kellogg protocol, the Corporate Incident Management Team briefed my senior management team and me on the situation. Based on the information provided, we made the decision to initiate a "pull and hold" with respect to our *Austin*® and *Keebler*® peanut butter sandwich crackers which contained PCA paste.

This involved two steps. First, we contacted customers that day and instructed them to pull these products from shelves until further notice by Kellogg so that the product would not be available for purchase. Second, we issued a press release advising consumers not to eat previously purchased peanut butter sandwich crackers because of possible risk of *Salmonella* contamination.

Two days later, on January 16, 2009, PCA extended its recall to include limited 2008 lots of peanut paste, plus additional lots of peanut butter. At that time, Kellogg escalated its pull and hold to a voluntary Class I recall of peanut butter cracker sandwiches back to July 1, 2008. We also recalled two snack-pack sized cookies which a co-manufacturer had informed us had been produced using impacted PCA peanut butter lots.

As PCA recalls expanded, Kellogg promptly expanded its recalls of impacted products. In total, more than 7 million cases of our products were recalled due to the PCA contamination at a cost of approximately \$65-70 million. We devoted significant staffing and resources to quickly trace our products, notify and inform customers and the general public, and execute our recalls to protect our consumers.

Since we first learned of the PCA investigation, Kellogg has worked closely and cooperatively with FDA, the Centers for Disease Control and Prevention (CDC) and local agricultural and health authorities in their investigation of PCA and potentially impacted Kellogg products. We immediately shut down manufacturing lines at our Cary facility which had used the PCA peanut paste, isolated other areas of our plant, and did extensive testing of our facility. It is important to note that all of our environmental tests of the Cary plant before the recall were negative for *Salmonella*. In addition, all of the

environmental tests done at the Cary plant in connection with the PCA investigation were negative for *Salmonella*.

We also worked closely with authorities to conduct a precautionary and extensive hygienic cleaning of all the lines in our plant that used PCA paste. All of the tests run after that hygienic cleaning have been negative for *Salmonella*.

We were deeply disturbed by reports that *Salmonella* was identified in two samples of our peanut butter cracker products. We reached out to the FDA and CDC for more information on those results and continue to cooperate with officials in their ongoing investigations.

Kellogg's Continuous Improvement

The PCA situation has shown that if a company chooses to ignore even basic food safety principles, food safety systems and protections can be compromised, whether those are individual company systems or the U.S. food safety system generally.

Our food safety program operates on the principle that food safety is a process of continuous improvement. In that spirit, and as a result of what we learned from this unfortunate situation, we have taken several immediate actions. We established new cross-functional Kellogg audit teams, including our Quality, Food Safety and Materials Management groups, to audit suppliers of high-risk ingredients, and have already completed on-site audits of our peanut and peanut paste ingredient suppliers. We are requiring suppliers to conduct environmental testing and monitoring in their plants to assist in identifying, assessing and correcting potential contamination before it becomes a

food safety problem. We are also strengthening our internal training and education across our supply chain.

Recommendations for Industry Improvements

The recent outbreak illustrated that the U.S. food safety system must be strengthened. We believe the key is to focus on prevention, so that potential sources of contamination are identified and properly addressed before they become actual food safety problems.

Attachment I outlines recommended enhancements which Kellogg believes would enhance the safety of the nation's food supply. You will note that we support several principles: (i) the formation of a single food safety authority under Health and Human Services that will give accountability to one agency leader for science, surveillance, research and inspection, with support from a science-based Food Safety Advisory Council; (ii) a requirement that every food company conduct a risk analysis and document their preventative controls, verification systems and testing results in a food safety plan that is subject to regular FDA review; (iii) annual inspections by FDA of facilities producing high-risk products; (iv) working with industry and government to align around a single food safety standard for evaluating facilities, with appropriate training and accreditation of auditors and auditing firms; and (v) ensuring that FDA has the right mix of intervention and enforcement powers.

Kellogg is firmly committed to working together with Congress, industry and other stakeholders to evaluate and advance these recommendations.

**Statement of A. D. David Mackay, President & Chief Executive Officer
Kellogg Company
Hearing on “The Salmonella Outbreak: The Role of Industry in Protecting the
Nation’s Food Supply”
United States House of Representatives, Committee on Energy & Commerce
Subcommittee on Oversight and Investigations
10:00 a.m. Thursday, March 19, 2009
2123 Rayburn House Office Building**

**ATTACHMENT I
KELLOGG COMPANY RECOMMENDATIONS FOR ENHANCEMENTS TO
U.S. FOOD SAFETY SYSTEM**

Prevention

Single Food Safety Authority within Health & Human Services (HHS): There is an opportunity to strengthen and maximize the efficiency of regulatory oversight by aligning food safety leadership within HHS. If adequately funded, there is a public health benefit to be gained if a single HHS leader has direct line control over science, research, surveillance and different inspectional units and staffs. This allows HHS to focus food safety resources on products and practices that may contribute to foodborne illness. In addition, a Food Safety Advisory Council comprised of government and industry food safety experts should be established and permanently funded to support development of enhanced science-based food safety policies and standards. We also support the Obama administration’s effort to create a new food safety working group to coordinate interagency food safety efforts.

Risk analysis and Food Safety Plans: The production of safe foods starts with prevention, which is accomplished by identifying potential risks in the food production system and developing a proactive plan to prevent or eliminate these risks before they become food safety issues. All food manufacturers should be required to conduct a risk analysis and to develop a food safety plan for FDA review. The plan should document appropriate preventative controls and verification steps. In particular, manufacturers of high-risk foods should be obligated to monitor their manufacturing environments for *Salmonella*, to keep a record of all *Salmonella* positive test results and their

corrective actions, and to make these records available during an FDA inspection. By requiring disclosure of positive *Salmonella* test results during inspection, the FDA can assess how the company responded and whether the appropriate corrective actions were taken.

Improve Current Good Manufacturing Practices (GMPs): Stakeholders in food safety have learned much since GMPs were last updated 22 years ago. Congress should mandate a deadline for the agency to update GMPs to reflect new information, particularly in the areas of training, allergen control, control of manufacturing environment (pathogen environmental monitoring) and sanitation.

International Food Protection Training Institute: Kellogg Company supports establishing an “International Food Protection Training Institute” to train government and industry inspectors. This Institute would provide a first-in-class, career spanning curriculum developed and implemented by the Association of Food and Drug Officials (AFDO). Inspectors would be trained to inspect against widely recognized food quality and safety standards to enhance the consistency of inspections.

Intervention

Annual FDA Inspection of Facilities Manufacturing High-Risk Foods: FDA must ensure all companies, big and small, are producing safe products. One way to accomplish this objective is to have all facilities which manufacture high-risk foods inspected regularly. Currently, many of these manufacturing facilities are not inspected on a frequent basis, leaving potential gaps in the overall food safety system. Consequently, we recommend that FDA perform an annual inspection of each high-risk food manufacturing facility.

Food Manufacturing Facility Audit Standard: Food manufacturers, retailers and consumers would benefit from a universal food safety standard for evaluating food manufacturing facilities. The standard should be developed through a transparent and open process. We support efforts to develop this standard and to train, certify and accredit third-party auditors and auditing firms to ensure that audits are conducted in a consistent manner.

Mandatory Recall Authority: Responsible food companies remove foods from the marketplace when there is a concern regarding their safety. Providing the FDA with mandatory recall authority would remove any obstacles that could delay or prevent the removal of potentially unsafe foods from the marketplace.

Response

Traceability of Ingredients: Congress should direct the FDA to work with food manufacturers, farmers and retailers to explore traceability systems, and to explore new technologies that can integrate different traceability systems without abandoning investments made in response to bio-terror laws.

Mr. STUPAK. Thank you, Mr. Mackay.
Ms. Isely, your opening statement, please.

STATEMENT OF HEATHER ISELY

Ms. ISELY. Good morning, Chairman Stupak, Ranking Member Walden, and members of the subcommittee. My name is Heather C. Isely, and I am executive vice president and part-owner of Vitamin Cottage Natural Food Markets, Inc.

We very much appreciate the opportunity to provide our input to the subcommittee on our involvement with the Peanut Corporation of America and to provide insight on how outbreaks like this one are dealt with by small-chain retailers.

Vitamin Cottage was established in 1955 by my parents. They started the business by going door to door in Golden, Colorado, selling whole grain bread and sharing nutrition information with people they met. I started working for my parents at the store when I was 9 years old.

Our goals have always been the same: providing exceptional customer service, extensive nutrition education, and the highest quality products at affordable prices.

For over 30 years, Natural Grocers has offered fresh-ground peanut butter. Our employees make peanut butter in the store by running dry-roasted peanuts through a small grinder. For the past few years, the dry-roasted peanuts for this product have been purchased from PCA from its Plainview, Texas, facility. Until the PCA outbreak, Natural Grocers has never had any adverse health issues associated with its peanut butter.

The timeline with respect to developments related to PCA-supplied products is well-known. For our part, despite continuing quality assurances from personnel at the PCA Texas plant, Natural Grocers quarantined its inventory of PCA peanut products on January 28th. On January 30th, Natural Grocers preemptively and voluntarily recalled all related products and began notifying customers to return all previously purchased fresh-ground peanut butter. We have detailed how we subsequently worked with the government authorities in our written testimony.

As a family-owned retailer, we are deeply concerned about the obvious breakdown in the regulatory system that brought about the PCA-based outbreak. We need effective laws and regulations that ensure we and our customers can buy food with confidence in its safety.

Again, I appreciate the opportunity to testify before the subcommittee and welcome any questions you may have.

[The prepared statement of Ms. Isely follows:]

**Testimony of
Heather C. Isely
Executive Vice President
Vitamin Cottage Natural Food Markets, Inc. (“Natural Grocers”)
Lakewood, Colorado**

before the

**Subcommittee on Oversight and Investigations
U.S. House Committee on Energy and Commerce**

**“The Salmonella Outbreak: The Role of Industry in Protecting the Nation’s
Food Supply ”**

Thursday, March 19, 2009

INTRODUCTION

Good morning, Chairman Stupak, Ranking Member Walden, and Members of the Subcommittee. My name is Heather C. Isely, and I am Executive Vice President and part owner of Vitamin Cottage Natural Food Markets, Inc. We are also known to the communities we serve as "Vitamin Cottage," "Natural Grocers," or sometimes just "The Cottage." I am pleased to be here today with our company's Director of Special Projects, Mr. Alan P. Lewis.

In light of the serious and tragic reasons for this hearing, we very much appreciate the opportunity to provide our input to the subcommittee on our involvement with the Peanut Corporation of America ("PCA") and to provide insight on how outbreaks like this one are dealt with by small-chain retailers. We are encouraged by President Obama's recent call for increased food safety and by Chairman Waxman's and this Committee's unfailing persistence in improving food safety.

COMPANY HISTORY AND PROFILE

Vitamin Cottage was established in 1955 by my parents, Margaret and Philip Isely. They started the business by going door-to-door in Golden, Colorado, selling whole-grain bread and sharing nutrition information with people they met. Philip and Margaret Isely found that the more health and nutrition knowledge their neighbors possessed, the healthier the food they would buy and eat. Their door-to-door business was successful enough that within a short time they were able to open their first retail location – a modest storefront that looked like a cottage. Gradually they were able to build their purchasing power to buy at lower cost, which allowed more customers to afford their healthy offerings. To this day, combining nutrition education with affordable, healthy foods drives our business model.

Our business is still privately held and family-owned and operated by my family. Together we strive to carry on my parents' legacy, and fifty-five years after they founded the company the goals of Vitamin Cottage – now Natural Grocers – remain the same. We focus on providing exceptional customer service, an extensive nutritional and health information service, and the highest quality products at affordable prices.

Natural Grocers has now grown from a tiny "mom and pop" business to a thirty-store chain with over one thousand employees in Colorado, New Mexico, and Texas. Whenever feasible, we add more stores based on the needs of individual communities. Our stores tend to be in the 10,000 square foot range, which is about 1/4 to 1/8 the size of a conventional supermarket. We stock approximately 10,000 carefully selected natural and organic food items, as well as an equally large selection of natural body care items, household goods, and nutritional supplements. We offer a full selection of healthy frozen foods, bulk foods, some cold prepared foods, prepackaged meats, poultry and fish, dairy products, and 100% organic produce. To maintain a scrupulously clean environment for our customers and to keep overhead costs low, we do *not* operate bakeries, butcher shops, cheese shops, hot prepared foods, salad bars, juice bars, coffee bars or other similar food preparation in our stores.

THE RECENT PCA RECALL

For over thirty years, Natural Grocers has offered organic peanut butter for purchase by our customers under its own “branded” label. We have small grinding machines in our stores into which trained employees place dry roasted peanuts; the peanut butter exits the machine into tubs labeled “Vitamin Cottage”, which are sealed. In recent years, Natural Grocers has sold about 5,000 pounds of fresh ground peanut butter each month. For the past few years, the dry roasted peanuts purchased for this product have been purchased from PCA. According to paperwork and verbal verification received from the company, all of this peanut stock was produced by PCA in their Plainview, Texas facility. Until the outbreak that is the subject of this hearing, Natural Grocers has never had any health issues associated either with its peanut butter or other private label products.

Beginning in November 2008, the Centers for Disease Control (“CDC”) identified a suspicious outbreak pattern of *Salmonella serotype Typhimurium* widely dispersed across the country. During their subsequent investigation, in cooperation with the Food and Drug Administration (“FDA”) and state public health agencies, the CDC linked the growing outbreak to peanut products produced by the PCA facility in Blakely, Georgia. On January 10th, 2009, PCA posted its first recall notice for PCA-made King Nut peanut butter. During January, PCA expanded its recall to all peanut butter products produced in Blakely, but publicly maintained that products from its other two plants were not implicated in the recall. During this time, Natural Grocers received extensive lists of hundreds of recalled products that potentially contained PCA-sourced ingredients. Daily (sometimes hourly), more products were removed from our shelves and recall list updates were posted both in stores and on our company websites. On January 21 of this year, FDA initiated investigations of PCA’s Texas and Virginia facilities. Natural Grocers was not notified of this inspection or any negative findings related to this inspection. Despite continuing quality assurances from personnel at the PCA-Texas plant, Natural Grocers quarantined its inventory of PCA peanut products on January 28th. On January 30th, Natural Grocers voluntarily recalled all unground and ground PCA peanut butter stock, and began notifying customers to return all previously purchased fresh ground peanut butter. On February 10, 2009, the FDA added a Vitamin Cottage fresh ground peanut butter recall notice to its web site.

Epidemiological Link to PCA-Texas Plant.

Of the total eighteen confirmed cases of Salmonella in Colorado, two patients presented the Colorado Department of Public Health (“CDPH”) with especially good data to trace back the outbreak. Based on what information was allowed to be released to us under patient privacy rules, both case-patients were four-year-old children with severe allergies, from different households. Due to the allergies, both families carefully controlled the diet to exclude tree nuts. Natural Grocers fresh ground peanut butter was reported to be one of the few peanut-related products the boys were allowed to consume, since it was a safe, single-ingredient product produced in a nut grinder used exclusively for peanuts. These reports, combined with our confirmation that we used PCA-Texas peanut butter stock in this product, led investigators to conclude that there existed a “possible association” between these two case patients, our fresh

ground peanut butter, and the PCA Texas plant. (Neither of these case-patients was reported hospitalized.)

According to our understanding based on conversations with the CDPH, there have been two hospitalizations of Colorado case-patients; one of these case-patients did not report consuming PCA peanut butter, while the other had eaten some PCA peanut butter along with several other suspect foods.

Of the dozens of peanut and peanut butter samples tested, there are only two positive tests for the outbreak strain of Salmonella. However, these samples are of limited value to the trace-back investigation because the samples were acquired from opened containers taken from households where salmonella was present.

Company Participation with CDC/FDA Trace-Back Investigation

Natural Grocers became one of the primary reference companies of the CDC, FDA, and the CDPH trace-back investigation for a number of reasons:

- The company had a long history of using PCA peanuts and maintained a record of lot numbers relevant to the outbreak.
- The company sold a large quantity of single-ingredient peanut product, which could help eliminate other ingredients as possible sources of the salmonella contamination. (Most other recalled products used PCA peanut products along with many other ingredients.)
- Our retail locations were very well maintained and clean, and we did not allow customers to operate (and therefore potentially contaminate) our peanut butter grinding machines. Trained staff following strict food safety guidelines in grinding the peanuts and cleaning the machines. (This is in stark contrast to other retailers, who allow unsupervised customer access to peanut butter grinders and to the bulk peanut stock.)
- Our peanut butter grinders were meticulously maintained and cleaned, so that extensive pathogen testing on the equipment successfully eliminated the machines as potential sources of the salmonella outbreak strain.
- We have one grinder in each store dedicated to peanut butter; it is not shared with other products (either intentionally or accidentally by customer usage).
- Of the fourteen or so initial confirmed Salmonella cases in our marketing area, six cases reported having PCA peanut butter from Vitamin Cottage in their pantries, and two of these patients were on carefully controlled diets and reported eating only PCA peanut butter as the only potential source of infection.
- Natural Grocers was willing and able to fully and proactively support all public health authorities, and dedicated several high-level employees to help the various public health agencies in the trace-back investigation.
- We were able to provide hundreds of PCA peanut samples from both sealed and open containers, with associated lot numbers, to FDA inspectors within hours of their request.
- Natural Grocers conducted its own extensive testing on unground PCA peanuts, unsold ground PCA peanut butter, and customer-returned PCA peanut butter in early February via federally accredited microbiology laboratories. (100% of these tests were negative

for Salmonella; all lab results are included in our documentation previously submitted to the Committee.)

FDA FOOD PROTECTION PLAN

We have carefully reviewed the 2007 FDA Food Protection Plan to see how we can support our government's efforts toward improved food safety. Below is a representative checklist of responsibilities and obligations that will fall to Natural Grocers when an improved food safety system is fully implemented. Please know that we are in full compliance for our part in this shared effort to ensure that American consumers can trust that the food they buy is safe to eat. The FDA Plan, is organized with three principles: Prevention, Intervention, and Response. Here is our current status in regard to compliance with these plans:

PREVENT Food-borne Contamination

- ✓ Source food domestically when possible.
- ✓ Source products and ingredients from known reliable companies who follow current Good Manufacturing Practices.
- ✓ Maintain food handling facilities that are compliant with US government, state, county and local regulations and guidance.
- ✓ Continually improve our internal food safety program and share significant advances with industry partners and the government authorities.
- ✓ Pay special attention to imported foods and be aware of potential criminal or terrorist activity.
- ✓ Institute sample testing of food products identified as high-risk.

INTERVENE at Critical Points in the Food Supply Chain

- ✓ Increase quality and frequency of food processing facility inspections.
- ✓ Assist in education employees and consumers about food-borne illness awareness and prevention at all levels of the food production system.
- ✓ Assist in educating food producers about food-borne illnesses.
- ✓ Report possible dangers present at a food processing facilities.
- ✓ Implement appropriate inspection, tracking, reporting, auditing and training programs.

RESPOND Rapidly to Minimize Harm

- ✓ Report positive pathogen tests within 24 hours and quarantine product
- ✓ Maintain adequate and accessible trace-back information beyond the shelf life of a product.
- ✓ Voluntarily recall potentially contaminated products.
- ✓ Provide the means to notify consumers within our reach about immediate dangers of potentially contaminated food once we have been notified of them.
- ✓ Cooperate with all investigations related to food borne illnesses.
- ✓ Allow emergency access to certain records and facilities related to a potential food safety threat.

We are proud to report to the Committee today that Natural Grocers is substantially compliant with key elements of the proposed Food Safety plan.

Affect of Proposed FDA Food Safety System on the Current Salmonella Outbreak

According to reports, PCA was able to operate “under the radar” of local, state and federal regulatory agencies while disregarding even basic food safety procedures. We agree with the FDA that the burden should be placed on private industry to develop and implement comprehensive food safety requirements as needed for their particular situation, equipment, foodstuffs and type of processing. We also agree that highly competent and empowered third party inspection and audit teams would probably have discovered, reported, and corrected alleged PCA violations and potentially avoided the current Salmonella outbreak. And we agree that at very least, a legal requirement to report positive pathogen results and destroy contaminated product, if complied with, would have at least limited the scope of the outbreak. Natural Grocers relied on PCA’s representations of compliance with Good Manufacturing Practices, its certificate of compliance with the National Organic Program from an USDA accredited agency (the highly respected Texas Dept of Agriculture) and other information to determine that PCA’s products were safe for consumption. However, a number of competent individuals – whether inside the plant, with government agencies, or with private companies -- appear to have had knowledge of material violations of food safety practices at PCA plants, yet failed to intervene.

Peanuts, until recently, have generally not been considered high risk for Salmonella contamination and would not have been subject to sampling and testing at the retail level under FDA risk assessment guidelines. Subsequent to this outbreak, we are sample testing each lot of peanut butter stock from our new supplier. Stock will not be released for use unless all tests come back negative.

As part of our existing internal food-borne illness alert system, we encourage our customers to report any possible bad health affects they suspect may be caused by the food we sell. We have received notice from three customers during the four months of this outbreak who stated they became ill with various gastrointestinal complaints, and had in the prior days consumed PCA peanut butter among many other foods. (The CDPH was informed verbally of these three reports.) After our store staff record the customers’ information, our Home Office staff contacts the customer for follow up if they have provided contact information. It is our opinion that given the information in these reports there would have been no reporting requirement under the proposed rules, because there was no confirmation possible via lab test, and the cases were unrelated in time, location, symptoms or duration of illness. Had these reports contained critical events, we would have asked the consumer to contact the FDA district office to make a formal consumer food-borne illness complaint. These reports are included in our responsive documents, and we would welcome guidance from the Committee on our responsibilities associated with them.

OUR APPROACH TO FOOD SAFETY

Natural Grocers was founded in 1955 for the sole purposed of improving our family’s and our neighbors’ health through better nutrition using a wholesome balanced diet. This was at

a time when a good working knowledge of nutrition was quite rare, and when highly processed foods with many questionable ingredients filled the shelves of most stores. Please see our website's statement on *What We Don't Sell and Why* – our first line of defense in regard to food safety is not to allow potentially dangerous substances into the foods we sell. Some of these substances are more immediately dangerous than others; however, when you keep other families as loyal customers over four generations, like we have, the subtle long term cumulative affects of even minute amounts of risky substances really, really matters. As a guiding principle, we will not sell a product today if it means possibly causing someone harm at any time in the future.

In addition to setting very high standards for the products we sell, we also set very high standards for the companies from which we buy. For each of the quality products on our shelves, it is certainly possible to find a much less expensive stand-in that might sell just as well but not really have the same nutritional value or meet our clean food standards. We only work with companies that have rigorous and transparent quality control standards. For critical categories such as meat and poultry, we personally inspect the operations and monitor their compliance with our own set of standards. These inspections are in addition to all of the health department and USDA protocols already in place.

Comprehensive Science-Based Approach to Nutrition and Food Safety

Our approach to food safety often puts us out ahead of government. We are often in the position of educating customers about why our safety standards are much more broad and strict than the government's.

When new research is published, we as a company proactively deal with potentially dangerous or unhealthy products. The government regulatory process is much more complicated – it has to encompass the values and concerns of hundreds of millions of constituents, many of whom have irreconcilable views. I will share a few examples of how Natural Grocers has already responded well in advance of new government rules being issued, based on the generally accepted conclusions of the scientific community.

The reason our internal food safety standards often exceed government standards is that as a private company we can approach food safety with a different starting question. We ask "Might this Substance do Harm?". This is a significantly different approach than required of public health authorities, who start by asking if an ingredient is "Generally Recognized As Safe." To be clear, we understand why legislators and regulators take a different approach to clearing new foods or medicines, and we are not criticizing that approach or suggesting it be modified. We would agree that one of the government's roles as the delegated representative of the common good is to prevent harm being done to the whole by any one individual's (or corporation's) acts. Nevertheless, when the government cannot demonstrate harm being done by a substance, it is unlikely to have cause to promulgate regulations.

While Natural Grocers fully supports and complies with this approach to creating policy that protects the public, we operate our business on behalf of a constituency that asks for a more stringent standard of protection. Clearly, our company's offerings do *not* appeal to everyone. To illustrate this point, try imagining the grocery store where you shop: it is probably almost as big

as a football field with row upon row of processed packaged goods lined up every three yards between the end zones and sidelines. In the stands surrounding the field are produce, dairy products, a deli, a meat and a fish counter. Now, imagine that store without any products that contain artificial colorings or preservatives. If you are doing this exercise right, all those shelves on the turf just lost most all of their products. Now take away dairy and animal products created with added growth hormones and antibiotics and take away produce grown with non-organic pesticides, herbicides, and cleaners (or co-mingled with produce that was). By now you should have in your mind's eye a huge empty stadium with row after row of empty seats, empty shelves, empty dairy cases, and empty produce aisles.

Natural Grocers will not sell just anything to turn a profit.. And for good reason, because our core customers, many of whom encounter difficulty shopping anywhere else, rely on us. Consider:

- Customers with severe gluten allergies prefer to shop where there is no gluten contamination in the air from an in-store bakery;
- Customers with compromised immune systems due to chronic illness or chemotherapy require almost sterile conditions to stay well. This is very difficult to accomplish with butcher shops and delis on site;
- Customers hypersensitive to odors can become nauseated in a conventional grocery. We do not waft heavy scents through our stores via cooking or artificially "improved" household goods;
- Customers who are uncomfortable with animal blood and carcasses appreciate not seeing or smelling fish and animal carcasses on display. We buy only pre-packaged meat, poultry and fish;
- Customers sensitive to the harsh chemicals found in conventional household items feel safer knowing our products are selected with their needs in mind; and,
- Customers who are vigilant parents of young children, or vigilant children of aging parents, who trust that we only stock foods that are good, clean, and safe for their vulnerable loved ones to consume.

For every potential customer who is unhappy that we won't sell them Tide Ultra detergent, just-baked sweet rolls or bowls of seafood "medley," there is another that is very happy that we don't. Another very important reason for avoiding store-prepared foods is that they tend to increase the cost of food while decreasing its nutritional value. Since our customers are often focused on the principles of clean food and good nutrition, and, tend to be quite frugal, our offerings lean toward simple, natural ingredients. Healthy food does no good if you can't afford to buy it.

CONCLUSION

Again, I appreciate the opportunity to testify before the Subcommittee, and welcome any questions you may have.

Mr. STUPAK. Thank you.

And thank you all for being here today and assisting us with this investigation.

We are giving you a document book there because I am going to ask about document number 48 and 49 in my first question.

You know, we have seen the photos and I think the chairman and Mr. Walden and others, we have all had the photos of the dead rodents and other filthy conditions at PCA. And you have heard what government investigators found when they went in to shut down these facilities: roaches, salmonella, contamination, and so much rodent excrement that they couldn't really quantify how much there was.

And I have read your statements, and I have listened to you here closely this morning. Essentially what you all are saying is that you didn't know about these problems at PCA. But my question is, why didn't you know?

I mean, I understand there was the audit firm AIB that inspected PCA and gave it very high ratings of "Excellent" or "Superior," but yet, in our investigation, we find AIB gives 98 percent of everyone they inspect "Superior" or "Excellent" ratings. But the companies—you didn't do your own inspections, like Nestle did, and therefore, you didn't find the problem.

So, in the audits there, if you look at number 48 and 49, if you would like, there in the document binder, the first one, 48, is, 2002, Nestle USA sent auditors to the PCA facility in Georgia where they found, quote, "the potential for microbiological cross-contamination" because of raw peanuts being handled in the peanut-roasting area. They found rodent droppings in the breakroom cabinets, live flower beetle activity, and dead insects.

Ultimately, they concluded in 2002, Nestle did, PCA was not in compliance with critical standards for housekeeping, sanitation, pest control, and they found PCA had no plan to address salmonella.

Nestle USA then went, in 2006, at the invite to go to PCA in Texas, in 2006, and found a failure to comply with pathogen monitoring and pest control standards. According to tab 49, the 2006 report, the auditors counted over 50 mouse or rat carcasses, concluding that the facility had, quote, "a serious ongoing problem with rodents."

As a result of these deficiencies, Nestle said no in 2002. In 2006, again they said no, and rejected PCA as a supplier, that they wouldn't buy peanut products from them.

The difference, it seems that Nestle didn't rely solely on an auditor that was selected by PCA and paid by PCA, which is an obvious conflict of interest. They conducted its own audits with its own experienced staff.

So I am going to ask each of you today, why didn't you do the same? You all talked about safety is the number-one concern, family-owned companies, you are doing everything you can to assure the safety, but it seems like you passed that responsibility to somebody else. So why wouldn't you have done the same thing? If this is your supplier of a critical ingredient, why wouldn't you go check it?

Mr. Kanan, do you want to start?

Mr. KANAN. Thank you, Congressman.

First, when we start out with a relationship, we require spec sheets from them. We rely on the FDA, that is supposed to be doing that. They certainly come visit us. We run a very clean shop and organization. They are very well-known in the industry. We had a continuing pure food guarantee from them. Throughout the relationship, we continued to ask for more things, like HACCP plans. We believed they had a HACCP plan in place. And we had COA showing negative results for salmonella by the end.

We were outraged—

Mr. STUPAK. No, I know, but why didn't you guys go check? If this is your main supplier to provide your peanut butter, you are putting your name on this, what, 5-pound pail and then up to 35 pounds, and goes to, like, nursing homes and that, why didn't you go check?

Mr. KANAN. We were distributor of this. I understand our name was on it, but we bought a closed container. And that is what we have to look at today. We have to start with the manufacturers. The distributors, the retailers down the line—

Mr. STUPAK. I will follow that up with a question.

Kellogg, you are a big company like Nestle. I am surprised you guys didn't at least have someone there with internal audits.

Mr. MACKAY. Yes, I think as we said in our written, but I will go through it, we use a multistep process. The—

Mr. STUPAK. Can you pull your mike up a little bit.

Mr. MACKAY. —third-party audit is one step in that. We also do risk analysis of ingredients. We bring the product into our labs to run it through our facilities, make sure it works, so we get first-hand experience with that. And we do get certificates of analysis.

Mr. STUPAK. Yes, but do you send people out to these plants?

Mr. MACKAY. Some we do, some we don't. The practicalities, when you look at—Kellogg is a big company.

Mr. STUPAK. Sure.

Mr. MACKAY. We have 3,000 ingredients, 1,000 suppliers. I think it is common industry practice to use a third party.

If you look at the situation here, AIB is the most commonly used auditor in the U.S. The AIB, as one of the many factors we use, is meaningful. The AIB audit confirmed several important food safety measures were in place at PCA. They had an environmental testing program. They did all microbiological—

Mr. STUPAK. Sure, but you didn't send anyone down like Nestle, like, to check PCA? You didn't send anyone down from Kellogg then?

Mr. MACKAY. We didn't at that point. But we have since, as of learning coming after, changed that—

Mr. STUPAK. After, yes.

OK, I am going to follow that up with a question, because you all have different standards here now on what you are doing. That is my next question.

Ms. Isely, any comment on that? You guys didn't send anyone? You are the family-owned one, that health is your concern. Did you guys send anyone to PCA in Texas or—

Ms. ISELY. We did not send anyone—sorry, Chairman.

Mr. STUPAK. That is all right.

Ms. ISELY. I am not used to this. I am from a small, family-run business. Sorry. I am a little bit nervous today.

Mr. Chairman, we did not send anyone to PCA. One of the things that, as a small, family-run business of a chain of retail stores, we have 1,300 suppliers of products to our stores for the 25,000 products that we sell in our stores.

Mr. STUPAK. Sure, but some of your products, like how animals are being treated and that, you said in your testimony you guys go send inspectors out. So I thought maybe you would go to PCA.

Ms. ISELY. Yes, we do, and I can comment on that now to explain the difference for us, is that we rely upon the government system and the good manufacturing practices—

Mr. STUPAK. Well, did you ever check with the government on Texas? Because you were getting it from Plainview, Texas, and Texas wasn't even registered. So did you check with Texas or the FDA to see if the place was even on anyone's radar screen, registered with anyone to produce food?

Ms. ISELY. No, we did not. We tried to rely upon the system in the United States. We purposely source our products from companies that manufacture in the United States because of the gold standard of manufacturing practices that do exist in this country.

What I was trying to say about the inspections for humane treatment of animals is, when there is not a government system in place, we do go out of our way to make sure that we inspect that what is on those labels is accurate and true.

Mr. STUPAK. Sure, but, with all due respect, in this case, because you got yours from Plainview, Texas, you didn't even check to see if it was even registered, the operation. So even if the government was doing its job, if you would have checked, you would have found that this Plainview, Texas place, which has all the dead rodents in it, wasn't even registered, was never registered or inspected by Texas or the FDA.

Let me ask this question. This is a June 2000 audit report from the Inspector General to Health and Human Services. And I have been on this committee now 15 years. I am sure Mr. Dingell and Mr. Waxman have been on longer than this. You know, how many years we have been trying to get standards.

You all have talked about all the things you are going to do now, and I compliment you on trying to do some things. But we can't have Kellogg doing one thing, Mr. Kanan doing something else, Ms. Isely, your company doing something else. Don't you think it is about time we have some standards as to what we look for when we go to these plants.

We were baffled last time that the State inspectors didn't pick up some things in the Georgia plant that were structurally wrong that encouraged, not discouraged, cross-contamination. Don't you think it is about time we had either Federal standards, international standards, since a lot of our food comes overseas, or at least CDC, NIH, some kind of standards that we all have to play by for inspections, testing of food and food processing places? Because you are all doing something different, and they are not going to mesh.

Mr. MACKAY. Congressman, I think one of the recommendations we made was that we actually developed consistent food manufacturing audit standards.

Mr. STUPAK. Yes, number seven, that was sort of like your standard number seven. But who should be in charge of that?

Mr. MACKAY. You know, I think if you start with the first recommendation we made, which was forming a single food safety authority within HHS and then having an advisory group that actually works for them on a scientific base, the reason for that is there are so many moving parts here that we need to bring the science to bear. Industry can work with that group to ensure that we are looking at the right standards for varying food facilities.

Mr. STUPAK. Sure. And it claims they have been doing that for years, since way back to June of 2002, and it never gets done. Either in industry or someone doesn't want to cooperate—

Mr. MACKAY. I think we are all here to try and work with you to encourage that we do move forward and make that change and we establish those standards. And I think there are a number of things we need to do consistent with that.

The other recommendation we have in here is that on high-risk foods that the FDA actually does an annual audit. And, within the context of that annual audit, all of the testing done by that facility is shared with the FDA when they go in and do that annual audit. It doesn't fix this unfortunate situation, but it certainly should enhance the food safety in the U.S. going forward.

Mr. STUPAK. Sure, I mean, on high-risk, we did the same thing in 1997; now here we are again in 2007. We had one in Georgia, and here we are 2 years later, same thing.

Mr. Walden, for questions, please.

Mr. WALDEN. Thank you very much, Mr. Chairman.

And I am glad you raised that issue of the IG report. Mr. Barton and I sent a letter to the FDA last week requesting documents and information on whether FDA has implemented the Inspector General's recommendations and how the FDA is implementing them. And, again, this goes back to June of 2000.

So we have some work to do on our end to make sure that the FDA is looking at these State controls on inspections and what is happening out there when they do delegate it out. So I hope you will help us in trying to get answers out of the FDA, Mr. Chairman, because I concur with your analysis on its lack of implementation.

I have a couple of just, sort of, "yes" and "no" questions for you initially and then a couple that will go into a little more depth.

Do you support uniform standards for third-party auditors, including standardized questions and formats, and government accreditation of these third-party audit firms?

Mr. KANAN. Yes.

Mr. MACKAY. Yes.

Ms. ISELY. Yes.

Mr. WALDEN. Thank you.

One of the things that has concerned me is—and it came out in some of the testimony today—when I was in the broadcast business, I was regulated by the Federal Communications Commission. The inspector chose when he or she was going to show up to look

at my public file, go out and look at my tower, review my equipment, have my operator show they could do an emergency alert test. They didn't call ahead of time to say, "A week from Thursday, I am going to come out."

Do you support third-party audits being announced or unannounced?

Mr. KANAN. I support them being unannounced.

Mr. WALDEN. Mr. Mackay?

Mr. MACKAY. I think as long as the logistics can work for unannounced, because there are so many audits that are going to be conducted, at some point maybe you have to give at least a day's notice or some notice, but if it helps the system by just going in unannounced, then we would support that.

Mr. WALDEN. Ms. Isely?

Ms. ISELY. We support unannounced.

Mr. WALDEN. OK. Thank you. I appreciate your answers to those questions. They are helpful.

Did your company receive a certificate of analysis or some representation from PCA that the peanut products sold by Peanut Corporation of America to your company were safe?

Mr. KANAN. We have in the past, yes.

Mr. MACKAY. Yes. In every batch we got in, we had a certificate of analysis, and all of them were negative.

Ms. ISELY. No, we did not.

Mr. WALDEN. You did not. OK. And did you seek those certificates or—

Ms. ISELY. Not—we did not seek those certificates. As a retailer—

Mr. WALDEN. You are more of a retailer. You are buying product to resell.

Ms. ISELY. We are buying product to resell, and so we don't seek those certificates of analysis on the food side. We really try to work with the system that exists.

Mr. WALDEN. Mr. Mackay, I have before me in—do you know what tab that is in? I guess it is not in the document book.

Mr. Chairman, without objection, I would ask that this document be put in the record, as well.

Mr. STUPAK. That is the certificate of analysis? No objection.

[The information was unavailable at the time of printing.]

Mr. WALDEN. And this is the one dated July 12th of 2007 from Peanut Corporation of America to Kellogg regarding coarse natural peanut paste, lot number 7192CNPB, as in "boy." And under the microbiological data, it shows results as negative for salmonella.

My understanding is that this certificate says negative, and yet this is one of the lots that showed positive on salmonella.

Mr. MACKAY. I am unconfirmed on the lot, but I know that every—we went back and checked every certificate of analysis we had received from PCA. Every certificate of analysis was negative.

And I think that just highlights how extremely difficult it is when you have an unethical and dishonest supplier to actually manage for this.

Mr. WALDEN. And do you think that the records from these independent labs that do the analysis to see if there is a problem with

the product, do you think those records, A, should be available upon inspection by the FDA?

Mr. MACKAY. I think any finished food records that show a positive, it could be helpful to actually present those to the FDA.

Mr. WALDEN. Ms. Isely?

Ms. ISELY. We would agree with that.

Mr. KANAN. Yes.

Mr. WALDEN. Because in one of our hearings it came out that I guess they have to go through the Bioterrorism Act in order to get access to these records. And that just seems preposterous to me. I don't understand it.

Do you think these ought to be electronically reported to the FDA when there is a positive hit?

Mr. KANAN. That would be very helpful.

Mr. MACKAY. Yes, I think that would be the best course.

Ms. ISELY. Yes, it would help us, as well.

Mr. WALDEN. And do you think there ought to be a requirement for this kind of testing to occur and for audits to occur?

Mr. KANAN. Let me understand your question again, Congressman. You are asking, do you think that mandatory testing should be required? On what kind of testing, salmonella?

Mr. WALDEN. You know, I am not an expert in the field. I would seek your counsel.

Mr. KANAN. Yes, absolutely—I agree with you, I think that would be very helpful to have mandatory testing on requirements that somebody says should be, you know, peanut butter, salmonella, for example.

Mr. MACKAY. I would clearly support, if a lab finds a positive test on finished food, they give that to the FDA.

One of the things that I think is critical when you understand the system is that prevention is really the key—

Mr. WALDEN. Right.

Mr. MACKAY [continuing]. To very strong food safety. And to prevent, environmental testing becomes one of the key steps in that, which is done much further upstream. Most companies that do environmental testing, as we do in all of our facilities, if we were to find any issue, we would take preventable action to prevent it actually leaking into the food stream.

So the only reason I worry is that, Congressman, the complexity, if you ask for every test, environmental as well as finished food, you potentially could overwhelm the safety and the FDA, and it may be impractical. I am not trying to be defensive, but it is—

Mr. WALDEN. No, no, that is fair. I am seeking your input, because we don't want to shut down the food chain; we want it to be safe.

Which you really lead into my next point, these very dramatic and disgusting photos that we have come about not from the third-party auditors, it is my understanding. And this is out of the Texas plant for PCA that show the dead rodents and the feathers and God only knows what else. This came about because of an inspection and—excuse me, an investigation.

My understanding is that, in your industry, when there is an audit, it is maybe a day long. And the company picks the auditor, and they can preannounce that they are coming. So they don't get,

potentially, into the detail level that an investigation that can go 3 or 4 days might actually get into. And it was the result of an investigation that found this.

So should audits be longer? Should they be more on the investigative side?

Mr. KANAN. With third-party audits, Congressman, they are at least a day or more at our facilities. FDA is a couple hours, 2 or 3 hours.

Mr. WALDEN. And that is FDA inspection, but what about investigation? Have you ever had one of those?

Mr. KANAN. An actual investigation?

Mr. WALDEN. Right.

Mr. KANAN. Not that I am aware of.

Mr. WALDEN. All right.

Mr. Mackay?

Mr. MACKAY. I think it is, rather than—one of the differentials here is our inspections, I think—if you have a high-risk facility or food ingredient, our recommendation—and we have already made this change internally—is to have a multifunctional team. Typically, they would take longer than a day, but even if it is a day, you have three, four people versus one person, and you have experts in a variety of different areas so they are actually doing as good a scan as possible.

We have said in one of the recommendations we have made that we believe that food safety plans should be developed for all facilities in the U.S.

Mr. WALDEN. And I have one more question. And I appreciate the chairman's indulgence.

Ms. Isely here is a retailer; could be any store in America. If she came to your company, Mr. Mackay, and said, "I need to see tests, I need to see all these things before I will sell your product," how would that work? Is that even—do retailers come to you and demand that?

Mr. MACKAY. Yes, they do. And sometimes retailers will demand a specific type of audit.

Mr. WALDEN. And how do you respond if it is Walmart or a big chain—I am not picking on Walmart—but a pretty big buyer with a lot of horsepower versus a small, independent?

Mr. MACKAY. For us, it wouldn't matter. Within the context of our facilities, we have standardized audits that comply with almost every criteria that retailers would ask for.

Mr. WALDEN. Is that the same, Mr. Kanan, for you?

Mr. KANAN. Yes. I mean, if a retailer came to us to ask us for our audits, it is all standardized. We would be able to give them—

Mr. WALDEN. And you do that? Your retailers come to you and ask that on a regular basis?

Mr. KANAN. Some do.

Mr. WALDEN. OK.

Mr. KANAN. Many don't.

Mr. WALDEN. So, regardless of size, they could ask you for that?

Mr. KANAN. Yes.

Mr. WALDEN. All right. Thank you.

Thank you, Mr. Chairman.

Mr. STUPAK. Chairman Waxman, for questions, please.

Mr. WAXMAN. Thank you, Mr. Chairman.

Mr. Mackay, you indicated you had a certificate of analysis showing that there was no salmonella in the batch that you were buying from Peanut Corporation of America. As I understand, the certificate of analysis is no guarantee that there is no salmonella; it is they have tested but it doesn't—and where they tested there was no salmonella, but there could be in the tub, some other place where there might be salmonella. And it turned out, to your misfortune, that it was an unscrupulous supplier that was providing this batch of peanuts to you.

But you indicated in your written statement that—you say that, “There is an audit finding that reported no concern that the facility may have had any pathogen-related issues or any potential contamination.” And I am quoting from your written statement.

I want to direct your attention to a March 2008 AIB audit report for PCA's Georgia facility. And, in this audit report—we know AIB is the group that did the audit for PCA. In this audit report, it says the following: “This facility had evaluated the processes and procedures and determined that no critical control points were present in the operation.” No critical control points.

Now, that, to me, is—when we talk about a HACCP, there has to be a plan. There has to be a plan for preventing salmonella. And they are saying there were no critical control points. Now, an obvious critical control point would be the roaster, because the roaster can kill the salmonella.

So, most manufacturers would very much see the peanut-roasting stage as a critical control point. But this audit said to you there are no critical control points. This means PCA looked at its peanut manufacturing process and looked at all of its procedures, and it determined they didn't have any critical control points, not even for killing salmonella.

Did you have a reaction when you saw that in the audit? Or did you even notice it? Don't you think that PCA should have designated killing salmonella at the roasting stage as a critical control point?

Mr. MACKAY. Firstly, I didn't see that particular audit. I think the audit I referenced, they—when we had gone through as part of our multistep process and looked at the third-party audit and looked at what AIB had given us in that audit, that they had quantified that they did have a food safety plan in place.

And my belief is, and one of the recommendations here is, that we should codify that all plants should have a food safety plan in place, because, really, that is the key to prevention.

Mr. WAXMAN. Well, we need to do that. You are absolutely right, we need to do that for the future.

But, in this case, you were relying on PCA to have this third-party audit. They had a third-party auditor who, in my view, clearly had a conflict of interest. They wanted to give PCA an audit that PCA would like. In fact, they even gave PCA an award that they knew PCA would like, saying they were superior in their quality, even though we know that is not the case.

So, if the audit was sent to you and said PCA didn't even have critical control points, that audit was telling you at Kellogg that

PCA did not have a plan to effectively kill salmonella. Peanuts are a high-risk product for salmonella. So I am sure you are aware and all of you are aware that there needs to be a clear plan to make sure that salmonella is stopped.

And I think that PCA was a bad company. They did bad things. And they were clearly ignorant because they wanted to be ignorant. But this indicates to me that Kellogg was pretty sloppy. You were just taking things for granted that PCA was going to do the right thing.

They gave you a report of their inspector. They hired the cheapest inspector they could possibly get. I think they paid this inspector maybe \$1,500. There are more thorough inspections that would have cost more money. The gold standard is a \$20,000 inspection. Well, I guess everyone should realize they would have been better off spending \$20,000 than going on the cheap, because it is \$70 million, I believe, is the loss for all of this as a result of their going on the faith that everything was going to be OK, without making sure they could stop salmonella and stop this sort of thing from happening.

Do you think that you were sloppy?

Mr. MACKAY. Congressman, I think we did everything we could do. When we looked at our multistep process, the third-party audit was a key part of it, but we did a risk-analysis assessment. We did actually take the product in and check it through our labs, and then we relied on a certificate of analysis.

And, as I mentioned, you know, managing for an unethical, dishonest supplier who is prepared to actually put people's lives at risk is something, as we have stepped back and learned from this, means that we have already changed our process. And that is why we are here trying to work with you to say there are a number of things we believe that we need to do.

Mr. WAXMAN. Well, let me tell you, there were some red flags that you should have noticed. I think you should have noticed that statement in the audit that said they didn't have the critical points. You didn't do what Nestle did; you didn't send your own people to the plant and inspect it. You relied on what ordinarily, I guess, would have been OK, but you didn't do that extra step that I hope you will now require to make sure that there is a process to prevent salmonella.

And, in that regard, I must differ with you. I think Kellogg was sloppy. I think PCA was bad. And I think the whole thing has resulted in a tragedy that could have been prevented.

Thank you, Mr. Chairman.

Mr. STUPAK. Thank you, Mr. Chairman.

Mr. Dingell for questions, please. We are just starting votes, but let's get some questions in.

Mr. DINGELL. Ladies and gentlemen of the panel, I am going to ask a series of questions that will require only a "yes" or a "no" answer. We will start with you, Mr. Kanan, and go across to Mr. Mackay and then Ms. Isely.

First, do your companies have best practices in place to ensure the safety of the products you receive from suppliers? Yes or no?

Mr. KANAN. Yes.

Mr. DINGELL. Do you, Mr. Mackay?

Mr. MACKAY. Yes.

Mr. DINGELL. Ms. Isely?

Ms. ISELY. Yes.

Mr. DINGELL. All right. Do these best practices include on-site audits of sanitary conditions and processing techniques of suppliers prior to and during your contractual relationship with them? Yes or no?

Mr. KANAN. No.

Mr. MACKAY. Sometimes.

Mr. DINGELL. Sometimes.

Ms. Isely?

Ms. ISELY. Sometimes.

Mr. KANAN. Do I get to say "sometimes," Mr. Dingell? That was a "yes" or a "no."

Mr. DINGELL. Yes, I have to do it that way because we have a very short amount of time.

Ladies and gentlemen, again, did representatives from your companies inspect sanitary conditions and processing practices of Peanut Company of America prior to your company contracting with that company as a supplier? Yes or no?

Mr. KANAN. I am sorry, I have to hear your question again.

Mr. DINGELL. Did representatives from your companies inspect sanitary conditions and processing techniques of Peanut Company of America prior to contracting with PCA as a supplier? Yes or no?

Mr. KANAN. No.

Mr. MACKAY. We relied on industry practice.

Mr. DINGELL. I am sorry?

Mr. MACKAY. We relied on industry practice. No.

Mr. DINGELL. OK.

Ms. Isely?

Ms. ISELY. No.

Mr. DINGELL. Did representatives from your companies inspect sanitary conditions and processing techniques of PCA while it was contracted as a supplier of peanut products to your companies?

Mr. KANAN. I am just having a hard time hearing you.

Mr. DINGELL. I am doing my best. Did representatives from your companies inspect sanitary conditions and processing techniques from PCA while it was contracted as a supplier of peanut products to your companies?

Mr. KANAN. We rely on industry standards, as well. So, no.

Mr. MACKAY. Likewise, we relied on industry standards and certificate of analysis.

Mr. DINGELL. Ms. Isely?

Ms. ISELY. We also relied upon industry standards. And, no, we did not inspect.

Mr. DINGELL. Now, prior to the outbreak of salmonella caused by PCA's products, were your companies aware of the unsanitary conditions present in PCA's processing facilities?

Mr. KANAN. No.

Mr. MACKAY. No, we were not.

Ms. ISELY. No, we were not informed.

Mr. DINGELL. So what, in effect, you did was to rely on Food and Drug Administration's inspections and on industry practices to see

to it, essentially, that you got safe products, and you were taken advantage of. Is that not so?

Mr. KANAN. That is not so. We required specification sheets. We believe the FDA was inspecting it and they were doing their jobs. We required continuing pure food guarantees. So I would have to disagree with you on that.

Mr. DINGELL. Mr. Mackay?

Mr. MACKAY. No. I think as we have talked, third-party audits, certificates of analysis—we had an unethical and dishonest supplier. I am perfectly unclear as to how you manage for someone who is prepared to put consumers at risk.

Mr. DINGELL. All right.

Ms. Isely?

Ms. ISELY. Mr. Dingell, was the question, did we feel that we were taken advantage of?

Mr. DINGELL. You were taken advantage of by a bunch of sharpshooters who didn't do a decent job.

Ms. ISELY. Yes.

Mr. DINGELL. And you relied on Food and Drug, and you relied on industry practices to see to it that you were safe. I don't find fault in you in that. I think you are entitled to do it. But I think you have found yourself in a bad position because the law did not provide you and the rest of industry and consumers the protections they needed.

Now, would an up-to-date registry of all food facilities operating in the U.S. or importing food in the United States have helped FDA to identify and respond more quickly to a salmonella outbreak caused by PCA's products? Yes or no?

Mr. KANAN. Sir, every time you speak, I seem to get interference. Was your question the required registration of facilities?

Mr. DINGELL. Up-to-date registration of all facilities.

Mr. KANAN. Yes, absolutely.

Mr. DINGELL. Mr. Mackay?

Mr. MACKAY. All facilities should be registered.

Mr. DINGELL. Ms. Isely?

Ms. ISELY. Yes.

Mr. DINGELL. Now, I believe food processors should have to notify the FDA when they begin producing products that they have not previously registered. Do you agree? In other words, that is a part of having an up-to-date registry of processors and the state of the processing that comes into your plants.

Mr. KANAN. The way I understand your question is I believe that every food facility should be registered in the country—

Mr. DINGELL. And it ought to be registered for all of the products that they ship?

Mr. KANAN. That is correct.

Mr. DINGELL. Mr. Mackay?

Mr. MACKAY. Well, I am not sure the system actually exists, so I am not sure you can rely—

Mr. DINGELL. It doesn't exist, but I am asking whether you think that that would be a protection to you.

Mr. MACKAY. Well, at the moment we wouldn't know whether a plant was registered or not, because I don't think it is mandatory.

Mr. DINGELL. Ms. Isely?

Ms. ISELY. Yes, we would support it, because we believe it would help protect small businesses like ours, particularly if there was a way to communicate whether or not people were in compliance.

Mr. DINGELL. Do you believe that Food and Drug has the resources and the ability to carry out its responsibilities in ensuring that products reaching your places of business and arriving ultimately at the consumers' doorstep are safe? Yes or no?

Mr. KANAN. Do I believe they have the resources, is the question?

Mr. DINGELL. Yes.

Mr. KANAN. I think they have the resources. They just need to refocus.

Mr. DINGELL. The question is, do they have them? Yes or no?

Mr. KANAN. I believe I answered your question.

Mr. DINGELL. I am sorry?

Mr. KANAN. I believe I answered your question.

Mr. DINGELL. I would just like you to tell me yes or no; do they have the resources to do the job or not? Yes or no?

Mr. KANAN. Yes.

Mr. DINGELL. You think they do?

Mr. MACKAY. No, I don't believe they do.

Mr. DINGELL. I am sorry?

Mr. MACKAY. No, I do not believe they do. I think that is one of the reasons why we are here today.

Mr. DINGELL. Ms. Isely?

Ms. ISELY. We do not believe that they have the resources necessary.

Mr. DINGELL. Now, would better trace-back capabilities have helped FDA to mitigate or to prevent this salmonella outbreak?

Mr. KANAN. Yes.

Mr. DINGELL. Mr. Mackay?

Mr. MACKAY. It is a difficult one. I believe they could have.

Mr. DINGELL. OK.

Ms. Isely?

Ms. ISELY. Yes.

Mr. DINGELL. Now, should testing on food products and examination and visits and investigation of plants that are shipping products in interstate commerce be subject to safety requirements and be performed only by a laboratory accredited by FDA? Yes or no?

Mr. KANAN. Yes.

Mr. DINGELL. Yes or no?

Mr. MACKAY. Yes, I believe labs should be accredited by the FDA.

Mr. DINGELL. Ms. Isely?

Ms. ISELY. Yes.

Mr. DINGELL. Could this crisis have been mitigated if testing laboratories had been required to send their testing results to FDA?

Mr. KANAN. No.

Mr. DINGELL. Mr. Mackay?

Mr. MACKAY. No. I think it is impossible to manage for an unethical and dishonest supplier.

Mr. DINGELL. Ms. Isely?

Ms. ISELY. It is difficult to answer the question. I don't believe that it would unless there was some form of communication to

businesses that may be in receipt of products that had tested positive.

Mr. DINGELL. So you all three are of the view that the FDA does not need to receive the results of the investigation of the testing laboratories. Is that correct?

Mr. KANAN. No, that is not true, because that was not your question.

Mr. DINGELL. OK. Should FDA have the authority to issue mandatory recalls of tainted foods?

Mr. KANAN. Yes, but I have a comment on that, if I may.

Mr. DINGELL. I don't have time.

Mr. Mackay?

Mr. MACKAY. Yes, we would fully support that.

Mr. DINGELL. Ms. Isely?

Ms. ISELY. Yes, we support that.

Mr. DINGELL. Now, we have agreed that the Food and Drug does not have the resources to do the job. Do your companies support or oppose mandating registration fees with which to fund increased inspections by FDA? Starting with you, Mr. Kanan.

Mr. KANAN. You are calling me here to ask my opinions, and I don't feel like I am able to—am I here for an opinion or for a yes-or-no answer?

Mr. DINGELL. I just want to hear, do you agree that they should have or they should not have?

Mr. KANAN. I will have you ask me that question again.

Mr. DINGELL. I am sorry?

Mr. KANAN. I need to have that question again.

Mr. DINGELL. Do your companies support or oppose mandating registration fees with which to fund increased inspections by FDA?

Mr. KANAN. We would not be opposed.

Mr. DINGELL. Mr. Mackay?

Mr. MACKAY. We would support coming up with the appropriate way to improve the U.S. food safety system and finding a way to fund it, and I think industry would support that. But a lot more discussion would need to take place as to exactly what that might mean.

Mr. DINGELL. Thank you.

Ms. Isely?

Ms. ISELY. I think that we would be in support of it. And I agree with Mr. Mackay's comments, that we have to investigate it, particularly to look at its impact on small businesses.

Mr. DINGELL. Thank you, ladies and gentlemen.

Thanks, Mr. Chairman.

Mr. STUPAK. Thank you, Mr. Dingell.

Ms. DeGette, for questions. We have 4 minutes, if others want to go vote.

Ms. DEGETTE. I just have a couple of questions because I can't come back, and I appreciate your indulgence.

I would like to ask you, Mr. Kanan, do you support the nine principles that Mr. Mackay said that we should adopt to improve our food safety system in this country?

Mr. KANAN. From what I heard, Ms. DeGette, I do support it very much.

Ms. DEGETTE. Thank you.

Ms. Isely?

Ms. ISELY. Yes, we support that.

Ms. DEGETTE. And I want to ask both of you—I want to start with Mr. Kanan. Have the sales of your company suffered as a result of being tied to PCA?

Mr. KANAN. We haven't fully had a chance to analyze it yet.

Ms. DEGETTE. What about you, Ms. Isely?

Ms. ISELY. I would say that we have not. The second that there was any possible association or problem, we immediately pulled the product because we were concerned for the health and welfare of our customers.

Ms. DEGETTE. Do you think the confidence of your customers would be increased if we improved all of these food safety standards that we have been talking about?

Ms. ISELY. Oh, absolutely.

Ms. DEGETTE. What about you, Mr. Kanan?

Mr. KANAN. Yes, absolutely.

Ms. DEGETTE. What about you, Mr. Mackay?

Mr. MACKAY. Yes, absolutely. I think anything we can do to strengthen confidence in the food safety system in the U.S. is going to be worth doing.

Ms. DEGETTE. And let me start with you, Mr. Kanan. Now, we are hoping and we are intending to pass comprehensive food safety legislation this year. But, barring that, you have a financial interest in your company in improving the safety of the food that you receive. Are you doing that?

Mr. KANAN. Are we—

Ms. DEGETTE. Are you instituting practices that will improve the oversight of the—

Mr. KANAN. Yes, we are.

Ms. DEGETTE. And what about you, Ms. Isely?

Ms. ISELY. Yes, we are.

Ms. DEGETTE. Can you delineate for me some of the specific things that you are doing?

Ms. ISELY. On the food side of our business, we have started a quality questionnaire that is in accordance with some of the Grocery Manufacturers Association's food manufacturing practices to do audits and make sure that any of our vendors are following those good manufacturing practices.

We are also, particularly in respect to the peanut products, roasted peanuts that we receive, we are testing for salmonella and requiring a certificate of analysis that is free of salmonella.

Ms. DEGETTE. And do you think you might expand that for other types of at-risk products?

Ms. ISELY. Yes.

Ms. DEGETTE. Now, you said you have how many suppliers?

Ms. ISELY. We have 1,300 suppliers.

Ms. DEGETTE. 1,300 suppliers. And what were your gross revenues last year?

Ms. ISELY. Our gross revenues last year were close to \$200 million.

Ms. DEGETTE. \$200 million. Now, do you have the financial ability to go out and inspect all of those 1,300 suppliers?

Ms. ISELY. No, we do not.

Ms. DEGETTE. And so what percentage of those do you think you can inspect?

Ms. ISELY. What percentage of those?

Ms. DEGETTE. Yes, because you said you are inspecting some meat suppliers and others.

Ms. ISELY. Yes, we do. We inspect our meat suppliers that make our animal supplies for humane treatment of animals, cage-free, range, grass-fed, access to pasture—

Ms. DEGETTE. Right, I understand that. Do you think it would be worthwhile, for business reasons and obviously your consumers' health, to expand that to inspections in some of the more at-risk areas like peanuts?

Ms. ISELY. We would like to see that in the food supply arena that the government systems that you are discussing putting in place, that they work. If you are asking in the interim period what is our intent, yes, we intend to be more vigilant. I don't know what percentage we will be able to visit.

Ms. DEGETTE. OK. Thank you.

Thank you, Mr. Chairman.

Mr. STUPAK. Thanks, Ms. DeGette.

Our time is up and for votes, too. So I guess we better hustle to the floor. We are going to recess till about 12:15. We have three votes on the floor. If we get back here at 12:15 promptly, we can finish up this panel and finish up this hearing before the next series of votes.

So we will stand in recess until 12:15.

[Recess.]

Mr. STUPAK. I am going to call the committee back to order.

Before questions from Ms. Sutton, let me just say that Mr. Walden asked that we put this March 11, 2009, letter to Frank Torti, Acting Commissioner, concerning the salmonella outbreak, by Mr. Barton, and Mr. Walden had signed it. Without objection, it will be made a part of the record.

[The information was unavailable at the time of printing.]

Mr. STUPAK. Next, turn to Ms. Sutton for questions, please. Ms. Sutton for 5 minutes.

Ms. SUTTON. Thank you, Mr. Chairman.

I have several questions, but I would like to begin with Mr. Kanan. I know that when you answered the question about supporting mandatory recall authority for the FDA that you wanted to say something in addition to the fact that you all support that. So I am going to give you this opportunity.

Mr. KANAN. Thank you, Congresswoman Sutton.

And, you know, I have a special feeling for you because a lot of my employees live in your district. So you can imagine how much this has affected all of us. So thank you for that question.

I do support a mandatory recall, but I wanted to express my, at least, concern or opinion that, if there was a mandatory recall by the FDA, would it have prevented another manufacturer or owner of a company like myself from doing what I did, in getting out 3 days in front of doing a recall on a presumptive positive on an open container of peanut butter? Would there have been another business owner like me that perhaps may have said, "You know what, let's just wait for the FDA to do it, they will get their results on

Monday, it is their responsibility,” and will everybody do that? Now, I don’t think I would. I still would have done it. But I am wondering—and I just want to ask this to you all—would that prevent anybody from doing an earlier recall?

Ms. SUTTON. Thank you, Mr. Kanan. And I appreciate that you answered that it would not have affected your decision to do it, because that is what? The responsible thing to do.

Mr. KANAN. Right.

Ms. SUTTON. So I appreciate you bringing up that point because it may mean that we have to do additional action to make sure that those who fail to do it, just because the FDA has that authority, you know, maybe there is some more punishment that needs to be put in place. Would you agree with that?

Mr. KANAN. Correct, I would.

Ms. SUTTON. I often hear in this committee and in related hearings that one of the reasons that the people are concerned about requiring test results to be reported to the FDA—first of all, do you all agree that positive test results should have to be reported mandatorily to the FDA?

Mr. Kanan?

Mr. KANAN. It sounds like that would be a very good idea, depending on the specifics.

Ms. SUTTON. OK.

Mr. Mackay?

Mr. MACKAY. Positive finished food testing should be reported to the FDA.

Ms. SUTTON. And it should be mandatory that it is done? It is not just “should be” as in a voluntary nature, but it should be mandatory that they have to report positive results, correct?

Mr. MACKAY. However it is done, I believe that finished food testing positives should be reported to the FDA. It is also true today that it is law that, if it is in commerce, you have to report it, in any event. But I do support that.

Ms. SUTTON. Well, I disagree with the assessment of what the status of the law is today, based on some other testimony here.

Ms. Isely, do you also agree that positive results need to be reported to the FDA and that we need to mandate that that is done?

Ms. ISELY. We absolutely agree with that. Our desire is that small businesses like ours can make decisions based on those tests and can have information that they need to make the decisions on what vendors they buy from.

Ms. SUTTON. OK. And the reason why I even bring up that subject—it is actually related to my first point with Mr. Kanan—is that I often hear from people in these hearings that we can’t require the reporting of testing to the FDA, for fear that people then won’t test. And I guess my response to that, sort of similar to the whole mandatory recall authority, is, then we need to take further action to make sure that they are required to test and provide some sort of accountability for the failure to do so. So, you know, this is a big conundrum.

And, Mr. Mackay, if I could just shift a little bit over to you, because I am struck by some of the testimony you have given here. You talked about that high-risk food, that it is your belief that the FDA should do an annual audit. Is that correct?

Mr. MACKAY. That is correct, yes.

Ms. SUTTON. OK. And you also testified that sometimes you do your own independent audits at Kellogg and sometimes you do not, because you have so many products. Is that correct? Was that your testimony?

Mr. MACKAY. Within the context of our own facilities, we do environmental tests, and we have a food safety plan across all of them. I was referring to, when we talk about the ingredients or suppliers, given that there are 3,000 of those, we have relied on industry practice, the third parties and a multistep process.

Ms. SUTTON. OK. But I am just asking you the question then—so you said that sometimes you do a third-party, independent audit. Sometimes, though, you send out someone from Kellogg, correct, to do the audit?

Mr. MACKAY. That is correct, yes.

Ms. SUTTON. OK. And you think that the FDA should be responsible for doing the high-risk audits, but why don't you think that it would be a good practice for Kellogg—because peanuts, obviously high-risk product—for Kellogg to also make that their standard, that if you are dealing with a high-risk ingredient, that you wouldn't do your own audit?

Mr. MACKAY. Congresswoman, it is really a practicality difference. For example, we have undertaken audits of all of the peanut and peanut paste suppliers going forward, and so has almost every other company that uses peanut-based products.

The implication has been that those companies are running so many audits for companies, they actually can't produce the product we all want. So, if we could get great standards, if we could have an FDA system where on high-risk plants they are actually doing an inspection that we can all rely on, it would be better for everyone. Because then they can actually—these audits, the comprehensive ones, can take a fair amount of time, and rather than duplicate those by hundreds of thousands of companies, if there is a set standard and an FDA audit of high-risk facilities, we should, I believe, be able to rely on that.

Ms. SUTTON. OK.

I would also just like to talk a little bit about that third-party audit. And you made a reference to the entity that conducted that third-party audit. And is that an entity that you use a lot?

Mr. MACKAY. If you are referring to AIB—

Ms. SUTTON. Yes.

Mr. MACKAY. I think AIB—and third-party audits, in general, are broad across the industry. I think AIB is probably the largest auditor in the U.S.

Ms. SUTTON. My question is, do you use them a lot?

Mr. MACKAY. I can't tell you exactly how many audits we use from them, but we would use them on a number of our raw material supplies, yes.

Ms. SUTTON. Would you please provide that information to me after the hearing?

Mr. MACKAY. Yes, I am sure we can get that.

Ms. SUTTON. OK. And, in light of all the things that have happened, are you still relying on AIB audits? After all of the informa-

tion that has been presented here today and in the past few months that has come out, are you still relying on AIB audits?

Mr. MACKAY. You know, if you look at the AIB audit, they actually did find the problems. The issue wasn't with the AIB audit. It was with the fact that PCA actually acted in a dishonest and unethical way. The audit by AIB identified the problems, and PCA did not act upon them.

Ms. SUTTON. Well, Mr. Mackay, I would suggest that some of the evidence or the information that has been presented here today creates great concern about the coziness of these third-party, so-called "independent" audits and the results.

And so, part of my question, again, was just whether or not you continue to rely on the audits by AIB.

Mr. MACKAY. Well, subsequent to this unfortunate event, we have undertaken with high-risk suppliers to conduct our own audits.

Ms. SUTTON. Thank you.

Thank you, and I yield back.

Mr. STUPAK. Thank you.

Mr. Braley, for questions, please.

Mr. BRALEY. Mr. Chairman, I want to focus on the costs of inadequate food safety inspections.

And I will start with you, Mr. Mackay. There are press reports that the peanut industry could lose as much as a billion dollars as a result of this salmonella outbreak. And that is a lot of money, but what strikes me is how little money it would have taken to prevent all this from happening.

We know that the inspections didn't work when they were conducted by AIB, the third-party auditor that PCA hired. And when committee staff interviewed AIB officials, they told us that those audits were standard good manufacturing practices audits, which are the firm's most basic audits that cost about \$1,000. But AIB also told the committee staff that they offer more rigorous audits, which they call the gold standard audit, that is much more intensive and costs in the range of \$20,000 to \$30,000.

So, Mr. Kanan, let me start with you. Did your firm ever consider acquiring a gold standard audit from AIB?

Mr. KANAN. We, every year, have done AIB with the good manufacturing practices one. And we have not—nor did I actually know about this gold standard \$20,000 audit.

Mr. BRALEY. Mr. Mackay, has Kellogg ever used a gold standard audit from AIB?

Mr. MACKAY. I can't—I don't know whether we have. I can tell you that, within the context of our own facilities, we are doing what you would term "gold standard" audits.

Mr. BRALEY. Ms. Isely, has your firm ever used a gold standard audit from AIB?

Ms. ISELY. Mr. Braley, I appreciate the question. We are a very small retail business—

Mr. BRALEY. Can you just answer the question, please? I don't have much time.

Ms. ISELY. No, we did not.

Mr. BRALEY. All right.

Another option that was available to all of you—and I think you alluded to this, Mr. Mackay—is paying your own audit staff to conduct an audit. And earlier in the hearing, we learned that another company, Nestle USA, did its own audit of PCA rather than using a third-party auditor hired by PCA. Nestle’s audits uncovered serious deficiencies, such as rodent infestation and inadequate pathogen monitoring. And, as a result, they refused to do business with PCA.

Do any of you know how much Nestle paid to conduct its own audit of PCA? Just answer “yes” or “no.”

Mr. KANAN. No.

Mr. MACKAY. No, but I would reflect that that audit was done in 2002. And audits, by default, are at-a-point-in-time inspections.

Mr. BRALEY. Well, we all know that things go up over time because of inflation. But we are talking about a billion-dollar impact on one segment of the food industry. And the numbers we are talking about, in the thousand-dollar range, seem fairly small by comparison.

Well, we asked Nestle, and here is what they said. They told us that they pay cost to their audits that they conduct. And counting the employees’ salaries, travel expenses, and other costs, they estimated that their audits of PCA cost \$1,800, which seems like nothing compared to the alternative. And both of those audits took 1 day to conduct.

Mr. Mackay, can you tell us, based on current figures, how much Kellogg calculates that this problem has cost it?

Mr. MACKAY. Currently, our estimation is between \$65 million and \$70 million.

Mr. BRALEY. Mr. Kanan, do you have any estimate of what this has cost your company?

Mr. KANAN. It is around a half a million dollars.

Mr. BRALEY. Ms. Isely?

Ms. ISELY. We do not have an estimate.

Mr. BRALEY. So for approximately \$1,800, each of your businesses might have discovered the disastrous conditions at PCA and avoided the million of dollars in recall costs and lost sales that you are incurring today, which seems like a very small investment in food safety up front and part of smart business practices.

So let me ask you this. Mr. Mackay, does your company have plans to change its auditing practices going forward?

Mr. MACKAY. We have already changed, as a learning from this, with high-risk ingredients. We are now conducting our own audits.

Mr. BRALEY. Mr. Kanan, what about your company?

Mr. KANAN. Yes, we have already changed, as well. We want to do more audits because of this situation that happened with our high-risk suppliers, which we have determined.

Mr. BRALEY. Ms. Isely?

Ms. ISELY. Yes, we have plans in place to change. Once again, we are a small retail chain. Where you say \$1,800 is a small amount of money, it is not for a business of our size.

Mr. BRALEY. Well, you also realize that one of the costs—

Ms. ISELY. And I agree that one of the primary issues for us is to ensure the health and safety of the people who buy food from us, and that is our primary concern.

But I also want to give input into the committee that is realistic when you are talking about small chain retailers and what they can and cannot do. Because it would be a disservice to the committee to say that we will go to the point where we would be out of business in order to inspect the 1,300 vendors.

Mr. BRALEY. Well, let's talk about that.

Your company has \$200 million in gross revenues, operates 30 stores in three States and employs approximately 1,000 people. Do you think it's worthwhile to risk the employment of those 1,000 employees by failing to take adequate safeguards up front and having the long-term costs risk bankruptcy for the company?

Ms. ISELY. No, we do not. But at the same time—

Mr. BRALEY. I'm going to reclaim my time because I don't have any time left. I just want to close, Mr. Chairman, by pointing out that one of the reasons that I founded the Populist Caucus was to emphasize consumer protection and corporate responsibility. And I think it's important at this hearing to acknowledge that we need to reward companies like Nestle USA, who do the right thing and to set best corporate practices. They operate a facility in my district in Waverly, Iowa, and I would like the record to reflect that they are a good example of what you do when you do things right.

And I yield back.

Mr. STUPAK. Thank you, Mr. Braley.

Ms. Schakowsky for questions, please.

Ms. SCHAKOWSKY. Thank you, Mr. Chairman.

First, I want to acknowledge that I think we're at the base of this problem. We're talking about a company that, as far as I am concerned, was headed by a murderer, somebody who knew that there was a problem and quite deliberately made a decision to send that product out.

I don't know, Mr. Mackay, if you've been here before. I know the other two, for sure, haven't. But we have. We've been here before with food that has, if not killed, definitely made a lot of people ill—spinach and peppers—and every so often we're here again. And so I just want to acknowledge the responsibility that I feel as a Member of Congress, and our responsibility to act.

But I also do want to take you up on what I have heard of your offer. None of us is absolved of some responsibility, and certainly, going forward, we have to be. And I did want to—because we had a private conversation, Mr. Kanan, and I do want you to tell me about that conversation with Mr. Parnell at PCA.

Mr. KANAN. Yes. I just wanted to clarify that.

And, Mr. Stupak, you had in your opening statement that—I had said in my opening statement that I personally talked to Mr. Parnell and I had asked him, We're hearing rumors of salmonella—when the Minnesota Department of Agriculture called me—we're hearing rumors, they're testing it, and I want to know from you, have you had any other problems with salmonella, have you had any other complaints, have you had any problems in the past? And he personally told me on the phone, No.

The e-mail you showed is actually 4 or 5 hours after that; that's when we started talking to him. And we said—that's when you hear about, Well, we're going to have to do the recall. And that's when he said, I think I'm going to go to church and pray.

So we were very up on top of this with him. But when you have someone that's going to act illegal and criminal, I still am just so surprised, and I don't know, bewildered on how to handle somebody like that.

Ms. SCHAKOWSKY. Well, let me just say, that's why I think we absolutely have to have the systems in place both at the FDA—but I wanted to talk to you about systems as well.

Do you think that, as part of your own company's reporting to you, you ask for any positive test results from your suppliers? Let me just ask each of you if that is a feasible thing to do going forward.

Mr. Kanan.

Mr. KANAN. Yes, that's feasible to do.

Ms. SCHAKOWSKY. Well, let me just get that, Mr. Mackay.

Mr. MACKAY. Anyone who provides us with raw materials, they would—normally, if they're being honest and ethical, give us a response by the third-party lab of the positive.

Ms. SCHAKOWSKY. Do you request that? Is that routine?

Mr. MACKAY. We request that as part of the certificate of analysis, yes.

Ms. SCHAKOWSKY. You do?

Ms. ISELY. Yes, it would be feasible to request it. Without the weight of the law behind it and in a company that is bent on malfeasance, those can be not given or they can also be fabricated.

Ms. SCHAKOWSKY. If they're not given, would you not feel that maybe this is not a company to do business with?

Ms. ISELY. I think what I was referring to is—I believe the question you asked, should they be sending you—if they were positive.

Ms. SCHAKOWSKY. Actually I'm asking, should you be asking for that?

Ms. ISELY. Yes. We can—we did ask for their test results from the Plainview, Texas, plant. And yes, we do request that.

My point was that our requesting it does not mean that they will necessarily provide us with the information if they have it, because there's no weight of law behind it. And additionally, if a company is bent on malfeasance, they can fabricate the test results and show you a negative result.

Mr. STUPAK. If I may, I don't mean to interrupt here, but, Ms. Isely, you are under oath. And you testified earlier that you never even asked for a certificate of analysis. How can you say you asked those questions at—

Ms. ISELY. Mr. Chairman, we asked it after—when we were talking to the Plainview, Texas, plant.

Mr. STUPAK. After the recall?

Ms. ISELY. After the recall, yes, sir.

Mr. STUPAK. Oh, not before. She was asking about before.

Ms. SCHAKOWSKY. I was. That it be part of your routine inquiry as business owners to ask for the test results in a certificate of analysis.

Mr. MACKAY. And can I just be clear? Because we get that on the certificate of analysis.

We have not, I don't believe, currently requested, if a supplier we're dealing with had any positives, that they inform us with those—even whether they're for us or someone else.

And I think earlier there was a question, should that be mandated to be given to the FDA? And I would support that.

Ms. SCHAKOWSKY. I'm not talking about the FDA now.

Mr. MACKAY. I'm with you. I just think I may have not answered the question appropriately.

Ms. SCHAKOWSKY. So—let me understand then. You did ask for that information or you did not?

Mr. MACKAY. We ask for the information on anything that is sent to us. We—I don't believe we've asked for it more broadly to say if any supplier that we deal with had a positive for anyone else. I would have to check that information.

So, in other words, anything we get that's coming to a Kellogg facility, we have a certificate of analysis, and we get that information.

In the case of PCA, it appears that they may have manipulated that information. But I would have to check whether or not we asked for it, if it's for someone else and just happens to be a positive.

Ms. SCHAKOWSKY. Did you ask for PCA to disclose positive results before the outbreak? Had you ever asked them previous positives?

Mr. MACKAY. As part of the independent third-party audit and the risk analysis that we go through with a supplier—

Ms. SCHAKOWSKY. Yes.

Mr. MACKAY [continuing]. That's all part of the questioning. And typically the third-party auditor will actually do that sort of evaluation; and in fact, I think AIB did identify some issues. And I think the issue really at the end of the day was, PCA did not take the corrective actions.

Ms. SCHAKOWSKY. And you didn't make sure that they did?

Mr. MACKAY. I believe we did everything we could. But, you know, I may be getting into an area where I don't have actually the clarity of data here.

Ms. SCHAKOWSKY. OK.

I know I'm over time. I thank you, Mr. Chairman for indulging me.

Mr. STUPAK. Mr. Sullivan for questions, please.

Mr. SULLIVAN. Thank you, Mr. Chairman. I want to thank the panel for being here. This question is for Mr. Kanan and Mr. Mackay and, I guess, all panelists.

Have you heard of the Global Food Safety Initiative and the audits required to be GFSI certified? GFSI audits do analyze HACCP plants in greater depth, require a greater length of time to complete, are more expansive and give a more accurate evaluation of a company's food safety controls.

Would you be willing to, one, be subject to a GFSI audit? And two, require them for suppliers of high-risk ingredients? And I guess we will just go—

Mr. KANAN. Congressman Sullivan, I've heard of it. I don't know the details much about it.

I would most willingly want to look at it and be a part of it. And as long as it's something that we could—that would be feasible for us, we absolutely would be a part of it. And if it was something

feasible for our suppliers, we absolutely would like to be able to request that of our suppliers as well. That would be great.

Mr. MACKAY. Congressman, absolutely. It started in 2000, and we have been using that in all of our plants, manufacturing facilities, for about 3 years.

As you look at—there are three reasons why we think GFSI is a great standard; and whether we adopt that for the U.S. food safety system, or something equivalent, we think it's a great benchmark. The standards are accredited, the audit firms are accredited, the auditors are certified. And it's just a much more rigorous process.

And I think there is a lot of discussion now with industry, even talking about how we take GFSI and potentially use it in areas like APEC. So I think that would be an excellent place for this committee to look because it actually does address many of the recommendations I've said, and they're already in place and formalized.

Ms. ISELY. We are unfamiliar with the document that you are referring to. We would be happy to take a look at it. As a retailer and not a manufacturer, I'm not sure if we would have the expertise to understand exactly all the requirements in it.

Mr. SULLIVAN. OK. All right, I've got one more.

The food production chain is very complicated and there are many players, including suppliers, processors, distributors and retailers. Should they have different responsibilities and controls for ensuring food safety?

Mr. KANAN. Yes, I believe they all should have different responsibilities and different levels of it. But my personal belief is, it should start with the manufacturer or the one who is actually making the product, sealing it, boxing it, casing it. That is where I think the emphasis needs to be, is on that portion of it.

I think there are things distributors can do and retailers can do in the supply chain to help. But the greatest emphasis has got to come on—with the manufacturer of the product.

Mr. MACKAY. I think the standards for manufacturers and suppliers should be uniform and consistent. And that's the only way we're going to ensure the safety of the food supply.

When you talk to retailers and distributors, I think that's a different situation there. I think the focus, from their perspective, is more on traceability and how quickly they can react if there is a problem in the food system.

But I think with the standards, good manufacturing practices, HACCP, et cetera, that really comes back to suppliers and manufacturers.

Ms. ISELY. We would agree with all the statements that have been made.

Mr. SULLIVAN. Well, thank you very much.

I yield back.

Mr. STUPAK. We will go a second round for those members who are here, because there are a couple questions I want to follow up on.

Mr. Kanan, you mentioned the e-mail that I had in my opening statement. And when Mr. Parnell wrote back and said, I'm sure it

is something we did, haven't heard anything yet, but we will let you know; did they get back with you?

Mr. KANAN. Well, that's—I mean, after that, that's when we said, We're doing the recall. And then we had to talk to them the next day and over the weekend; and it was a constant——

Mr. STUPAK. Right. I recall you are the first company that started the recall on the peanut butter. Did you notify the FDA when you got this e-mail?

Mr. KANAN. The FDA had already been a part of this whole process for the day. I can't remember the day of that e-mail, if that is the Friday——

Mr. STUPAK. January 7. Wednesday, January 7.

Mr. KANAN. Wednesday. Yes, that was upon the first——

Mr. STUPAK. Right. Did you ever give them the e-mail?

Mr. KANAN. I don't know if we did or not, to be honest with you, sir.

Mr. STUPAK. OK. You said to do independent testing now for food safety? You do food testing now of your peanut butter?

Mr. KANAN. Yes. We are doing—with the new peanut butter suppliers, we are requiring a whole new set of standards for that as well.

Mr. STUPAK. But do you do testing over and above what your new suppliers give you?

Mr. KANAN. I do not know if we have tested the peanut butter for salmonella again or not. But we're——

Mr. STUPAK. So you could be basically in the same position you are in right now?

Mr. KANAN. No.

Mr. STUPAK. Hopefully, not a few years from now, like we have been. But why weren't you? If you are not doing independent testing, why wouldn't you just end up in the same situation if you are relying on third parties?

Mr. KANAN. Well, no. I mean, we are—I want to make sure I'm answering you correctly.

Mr. STUPAK. Sure.

Mr. KANAN. So you have to bear with me just for a moment.

Mr. STUPAK. A little bit. I can't give you a lot of time because we have 5 minutes.

Mr. KANAN. We are doing our own testing, and we're reevaluating the suppliers. We're looking at their AIB audits.

Mr. STUPAK. You are doing your own testing. So you are dealing with peanut butter. The problem is salmonella. Do you test independently from your supplier for salmonella?

Mr. KANAN. I don't know if we have yet or not.

Mr. STUPAK. OK. So technically we could be back to where we were 2 years from now. Hopefully not, but we could be underneath this scenario.

If your company comes across—in your independent testing, if you come across a positive for salmonella, you've indicated PCA should have notified the FDA. How about your company? Should you then be responsible for notifying the FDA?

Mr. KANAN. Oh, yes, absolutely. We absolutely would.

Mr. STUPAK. How about you Mr. Mackay? You do independent testing now. If you found positive tests for salmonella or E. coli on

spinach or whatever it might be, do you think your company has a responsibility to notify the FDA?

Mr. MACKAY. Yes, I believe so. We have started as a learning on this from all high-risk ingredients, doing our own multitask audits.

But, yes, I would agree that if you find in the finished food a positive test, the FDA should be notified.

Mr. STUPAK. How about you, Ms. Isely?

Mr. MACKAY. I beg your pardon?

Mr. STUPAK. I asked Ms. Isely the same question.

Ms. ISELY. Yes. We have started our own testing on the roasted peanuts. And we believe if there is a positive test, we should notify the FDA.

Mr. STUPAK. OK. In this PCA thing, it's my understanding—and we read in your testimony that none of you hired PCA—or I am sorry, you hired PCA, but you didn't hire AIB. Is that correct, Mr. Kanan?

Mr. KANAN. Well, we hire AIB for our own facilities.

Mr. STUPAK. OK. So how about for Georgia?

Mr. KANAN. As far as requiring our supplier to have somebody?

Mr. STUPAK. Right.

Mr. KANAN. I mean, we ask for their third-party audits.

Mr. STUPAK. So you use AIB or—

Mr. KANAN. We don't specify currently who to use.

Mr. STUPAK. Mr. Mackay, how about you?

Mr. MACKAY. I think there are three or four auditors that we would be comfortable with companies and suppliers using, and AIB was one of them. Probably—

Mr. STUPAK. PCA picked them then?

Mr. MACKAY. PCA picked them, yes. They worked for PCA. They don't work for us.

Mr. STUPAK. Are you still comfortable using AIB?

Mr. MACKAY. You know, as I think we have looked at AIB, they actually identified the problems. The issue here is an unethical and dishonest company that actually ignored many of the findings that AIB highlighted to them.

Mr. STUPAK. But also, here, my understanding from listening to your testimony was, there were different things—like you asked AIB to do a GMP, good manufacturing practices. But you could have asked them to dig deeper, as I think Mr. Braley and others pointed out.

It would have cost more money, right? It would have cost a higher test, like \$20,000 to do a salmonella testing as opposed to just good manufacturing practices, correct?

Mr. MACKAY. Yes. Well, one of the learnings I think from this from our perspective is that with high-risk ingredients—and we are now doing our own internal and more significant tests, which are more consistent with GFSI.

Mr. STUPAK. But before the salmonella outbreak, you could have asked PCA to—or AIB to do a more extensive testing for salmonella.

Mr. MACKAY. We could have. And I think you know I would say that what—we thought at the time we were using industry best practice. We have a multistep process including a third-party audit and the CofA and the risk analysis.

Mr. STUPAK. Sure. But Georgia plants—

Mr. MACKAY. Yes.

Mr. STUPAK. In 2007, Conagra—was it Peter Pan or Skippy peanut butter? Whatever it was, we had the same thing 2 years ago. Wouldn't that have put you on an alert to ask for more robust testing, not just of what's going on in the line, but actually the test results and do testing for salmonella?

I mean, this is all in the same spot. Basically 18 months later we have the same thing.

Mr. MACKAY. Yes. It was our understanding, through the AIB audit, that they were doing environmental testing. And when you look at Conagra, environmental testing was really the key there, because the issue was—

Mr. STUPAK. Testing is different than food safety testing; is it not?

Mr. MACKAY. There are a combination. Environmental testing is something you do at the start of the process to try to mitigate against anything actually making it into the food. The final check is, you have a certificate of analysis on the final food to make sure there is no pathogen in the food before it's shipped to us.

So it's a combination of both of those things that if they had been followed appropriately, we believe would have potentially mitigated against this.

Mr. STUPAK. I guess the part that bothers me—Kellogg's, you are a big, big corporation, many products. It unfortunately cost you a lot of money because of this recall. But yet you put PCA in the driver's seat. You tell them, Oh, use any one of these people; we rely on you.

You don't do independent testing. But without you, there is no PCA. I mean, you are the guy who—you are the company that is the monetary giant here. You could control the suppliers better if you wanted to because if you are not buying their product, it's going to be harder for them to stay in business.

I would think that a large corporation like yourself—you are all big corporations, actually—you would have more—you could have used your financial leverage to make sure some of these things we see now, in hindsight, could have been done to prevent the salmonella, especially since we had peanut butter salmonella as an item 2 years earlier.

I'm baffled by that.

Mr. MACKAY. I think, in hindsight, you are right. We have changed our process and we are doing our own testing.

I mentioned earlier a potential practicality issue here. When you look at the size of the supplier in the context of Kellogg, we bought, I think, \$5 million to \$10 million annually of product from this company. We probably spend in excess of, I think, \$3 billion or \$4 billion on raw materials. So it was a very small supplier.

And the industry best practice is to use third-party audits. We did supplement that with a risk analysis, and we did mandate certificates of analysis. And unfortunately a company that is not honest and ethical can mitigate against even the best systems.

Mr. STUPAK. Yes. But my question was industry standard.

When Nestle goes through and finds the problems—even Mrs. Field's cookies, we have documents in our binder there that they

found it, and they're an even smaller company, with the PCA, and just said, Man, these are bad practices; we're not going to use them.

I hope that's not the industry standard.

Mr. MACKAY. I'm not trying to be defensive.

There are hundreds of companies involved here, so all of us, if you like, are partially at fault for potentially relying on a system that I'm hoping that Congress will work with industry to actually enhance and improve, because that's the way we're going to actually make our food system stronger.

Mr. STUPAK. Well, President Obama has put more money, or proposed more money for the Food and Drug Administration, about \$1 billion more, about \$200 million new money for food safety. But everyone tells us it's still not enough; they need at least \$350 million per year for the next 3 years plus about an 18 percent increase every year after that for another 5 years to get up to par for food and drug safety. That's why we have the global food safety bill that Mr. Dingell, Mr. Pallone and myself have written.

Would you be in favor then of those registration fees? Not only do you have to register a plant like PCA, whether you are in Plainview, Texas, or in Georgia, but a registration fee to be put on these companies so we can finance this rigorous inspection system we're all hoping for and wishing for so we stop the food-borne illnesses?

Mr. MACKAY. Yes. I think what I would say is, Kellogg—food safety is paramount to Kellogg.

And—I think they are all reputable food companies, and I think the industry would embrace, how do we play an active role in ensuring that we can help, whatever the funding dynamics are, to ensure we do enhance the food safety system. I don't know exactly what that might mean. But I know that the industry would, and Kellogg would, certainly, be prepared to step up.

Mr. STUPAK. Including registration or inspection fees?

Mr. MACKAY. Whatever the final determination might be, whatever makes the most sense.

Mr. STUPAK. Thank you, Mr. Mackay.

Mr. Walden for questions.

Mr. WAXMAN. Thank you, Mr. Chairman.

Mr. Mackay, let me go to you. How many suppliers does Kellogg's have?

Mr. MACKAY. We have 3,000 ingredients, about 1,000 suppliers.

Mr. WALDEN. One thousand suppliers, 3,000 ingredients. And you require inspections, audits, from all of those suppliers?

Mr. MACKAY. Yes. We have a multistep process that we use in actually accrediting every supplier, including a third-party audit, including an analysis of risk, including certificates of analysis.

Mr. WALDEN. And have you worked with AIB? They're one of them, I think you said, that is one of the gold standards, right?

Mr. MACKAY. Well, they are one of three or four, as I understand it, accredited auditing firms in the U.S. that we have on our list as being acceptable to use by our suppliers to do the independent third-party audits.

Mr. WALDEN. All right.

Chairman Waxman stated that Kellogg's relied on procedures that are normally OK and did not, in this instance, take extra

steps that he felt were necessary to catch or personally inspect PCA.

Is it practical or cost effective to take these extra steps? I think that's one of the things I am struggling with is, where in the food chain, literally, is it most effective to step in? And I'm trying to figure out—I have a little company—or I have a number of them in my district and State that have been affected. They're food producers. They have had to do the recalls.

I think the one out in Union, Oregon, Rock Creek Nut, that, you know, used some nuts and put them both in trail mix and chocolate clusters. I cannot imagine a company in that tiny little town to have the resources to go order inspections at PCA.

How do we get to the point where, if you are the one producing the next step in the product development, you can count on what you get to be safe?

Mr. MACKAY. Yes. I think I'd refer—as I'm looking at the nine recommendations we made, each one of them actually builds on the other, so it's not like you can draw on one.

But I think if I pulled it to the development of food safety plans for every food facility as being mandatory; we're hoping consistent manufacturer audit standards as being another—actually having the FDA inspect what they would determine through the council as high-risk foods and/or ingredients, mandating that when they do those annual inspections, that if there are any test results within that facility, they're turned over to the FDA—I'm talking environmental now more than finished food. I think, in combination, all of those things, plus mandatory recall and traceability, are going to be required to actually improve the food safety system in the U.S.

Mr. WALDEN. Because—I'm a little sympathetic toward Ms. Isely here because, as a retailer, I think it would be almost impossible—it's hard enough running your retail outlet, then to think that every product you get in you have to test or something like that.

Somewhere upstream of that she should be able to know that when it comes to her store from your company or your company that it's safe. Otherwise you go next, what? To the parents, You have to test it before you eat it? I mean, at some point here it gets ridiculous.

Mr. MACKAY. Congressman, I agree. I think that's why we have a comprehensive overhaul of the current system. And I think the steps we've put forward—and I know a number of these have already been in what Congress is trying to pass—I think will make a significant difference in food safety in the U.S.

Mr. WALDEN. So what stage in the production process would you say is most important? Which one has the greatest likelihood of detecting a problem? I mean, if we had to focus on here are the top two places you need to go, what's the order?

Mr. MACKAY. Well, I think you've got to break it down. The first one is, if we're buying ingredients, then you need a comprehensive system that ensures that those ingredients when they come into our plant are actually safe. Now to include the last step on that is the certificate of analysis. In this case, we had—

Mr. WALDEN. You had one—

Mr. MACKAY. We had those. But it's very hard to manage for an unethical company.

Once we have the raw material and assuming that it is safe, then within the manufacturing process, environmental testing at the very beginning of that and all the way through food safety plans, whether it's HACCP or an equivalent, is absolutely essential because if you detect something early on, you can avoid its getting into the finished food.

Mr. WALDEN. Right.

Mr. MACKAY. That's absolutely critical. That's why companies do—and GFSI, these are audits that are so important.

Once you have the plant running, checking for environmental is really critical to make sure you can rectify any issues that might happen.

Mr. WALDEN. And I have a question for both you and Mr. Kanan.

You tested your products that you got from—the ingredients which came from PCA at some point after this was known, right?

Mr. MACKAY. We relied—

Mr. WALDEN. The recalled product.

Mr. MACKAY. Oh, on the recalled products?

Mr. WALDEN. Right.

Mr. MACKAY. I think the FDA has done all sorts of tests.

In the facility where the sandwich crackers were made—for example, we did over—last year, over 300-plus environmental tests, all negative. The FDA has come and done massive amounts of tests, all negative.

Mr. KANAN. All the tests we did on that, Congressman Walden, all turned up negative.

But the interesting thing I'd like to talk about real quick: When that open container was tested, they took 13 scoops of peanut butter and tested each one differently, only 4 of the 13 turned up positive.

All of the products we tested were negative. I never heard what FDA found out about—

Mr. WALDEN. Did you ask?

Mr. KANAN. Yes.

Mr. WALDEN. And they won't reveal it or what?

Mr. KANAN. They just haven't gotten back with us.

Mr. WALDEN. You don't know the answer to that?

The other question that I wanted to get to, and then I will let you finish up, because I will forget it otherwise. You said in your testimony, when you first got wind that there was a problem, that you asked FDA to test the product and they didn't. Why, did they tell you?

Mr. KANAN. I was baffled at that, honestly. I don't know what their procedures or policies are. I was asking them, please take it and test it because I want to know.

Mr. WALDEN. Sure.

Mr. KANAN. If not, I'm going to do it anyway.

Mr. WALDEN. Did they say that's your responsibility and not ours? Or did they have an answer?

Mr. KANAN. They didn't have an answer.

Mr. WALDEN. But then they came back?

Mr. KANAN. They came back the next day. Maybe they didn't have—weren't instructed by their superiors at that point. I don't

know. It didn't make sense to me, but I wasn't going to, you know, be questioning them at that point.

Mr. WALDEN. Mr. Chairman, it would be a good follow-up I think some time with the FDA as to why they didn't do that. I mean, I would think that if you are a distributor or a producer, and you think you have a problem—

Mr. KANAN. As a distributor, we obviously had the product right there.

Mr. STUPAK. The next day, didn't they come back?

Mr. KANAN. The next day they came back.

Mr. WALDEN. Only after they discovered it in another container, right? Or something like that?

Mr. KANAN. I don't know why they didn't—why they didn't take it the first day versus the second day.

Mr. STUPAK. Did it the second day but not the first day; I know it was in your testimony.

Did you ever find out the results of those?

Mr. KANAN. Never did.

Mr. WALDEN. That's the other issue. He hasn't been able to get the results back from the FDA, which seems odd.

Mr. KANAN. But it's going to be interesting because most of that was negative. And I think it's—that's the thing about salmonella, finding that in peanut butter. It lives in pockets, and—

Mr. WALDEN. That's what we've learned. And that's why I think so many of us were so offended when PCA got a positive, then they sent another sample out and got a negative and then said, Cut them loose.

Mr. KANAN. Somebody earlier had said that PCA was ignorant. I think they were very smart and they knew exactly what they were doing to try to get around that system. They knew that they could probably reblend the peanut butter and retest it because, look, 4 out of 13 came back. Odds are you are going to get a negative.

Mr. WALDEN. That's one of the great things on this committee, you learn a lot about things you never thought you would learn about. And that's one of them, that it's almost random in peanut butter whether you get a positive or a negative sample. That's why the law says, if you get a positive sample, you are done.

You can go sample again and try to figure out what went wrong and where it is in the system, but you do not ship that.

And we have the e-mail that indicated they—at least from my reading of it—knew pretty clearly what they were doing, and shipped out peanut butter once they got a negative after they had gotten a positive. And that's absolutely wrong.

Mr. KANAN. To Mr. Mackay's point, how do you stop somebody from being crooked?

Mr. WALDEN. And I guess—and then I will quit here because I have gone over my time. But that's what I'm struggling with.

I don't want to overreact and regulate to the point where you can't produce food and then what do we do? Have it all imported, and we will have no idea what's in it; we know about that from our other hearings.

So I want to get a balance here that works, that gives us as much security as we can in our food chain, but doesn't blow up our whole system because it has been working pretty well, frankly.

I realize there are these issues we've dealt with, and that's where we're trying—I think we ought to home in, be careful.

Your recommendations, Mr. Mackay, are most helpful and all of your input has been most helpful for me. We've got a separate bill that's bipartisan that would address this, I think, in a constructive way, too; and hopefully we can get together on a common strategy here.

So thank you, Mr. Chairman. And thank you to our witnesses.

Mr. STUPAK. Well, thanks. I guess one thing—how to get to it—I think there's a responsibility of food processors to ask the question. It's my understanding from the testimony we've gone through here for the last 3, 4 hours, and no one asked the question, did you ever have a positive? No one asked the question of PCA.

Mr. Mackay, that one document you showed us, the certificate of analysis which says no salmonella, in fact that lot did have a positive salmonella. I'm not saying to question every COA, but I would think someone would ask the question.

And the reason why you are here, and I don't want to confuse the record, like Ms. Isely and you, Mr. Kanan, you are processors; you are not just strictly retailers. So who has the ultimate or the final responsibility?

Mr. KANAN. We're the distributor with this product. That's why I kept saying, it's got to be the manufacturer.

Mr. STUPAK. You get the peanut butter from PCA. You slap your name—

Mr. KANAN. No. We didn't touch it. They put the label on. They sealed the case. We just bring it in.

Mr. STUPAK. It has your name on it. Don't you have some responsibility to make sure—

Mr. KANAN. I didn't say we don't have any responsibility. In this case, I'm the distributor. And I really think the biggest point in common with the manufacturer, we've got to help the manufacturers make better products so retailers, like Ms. Isely, and distributors like myself and the thousands of—

Mr. STUPAK. I believe Ms. Isely still processes the peanut butter. The only problem that you had was in the peanut butter that you are grinding in your stores, right? Wasn't that it?

Ms. ISELY. That's not the only problem we had.

Mr. KANAN. Retailers and the distributors in general, the biggest responsibility has got to come with the manufacturer.

Mr. STUPAK. Really.

Mr. KANAN. It starts there and ends there. It's sealed and closed.

Mr. STUPAK. Don't you have some responsibility since you put your name on it, and you are the one who puts it in the—

Mr. KANAN. I'm not saying I don't have that responsibility. But—yes, absolutely, but to help fix the system, Congressman, to help fix it, we've got to focus mainly on the manufacturer.

Mr. STUPAK. OK.

Let me ask this question, Mr. Mackay, if I may. Has Kellogg ever told suppliers they do not need to do finished product testing and, instead, just need to do environmental testing at facilities? Have

you told your suppliers, you don't have to do the finished product testing, just do your environmental testing?

Mr. MACKAY. I don't believe so, but I would think not. We can get you an absolute answer, because I don't want to put it on record and find that I'm wrong.

But my belief would be that that would not be the case.

Mr. STUPAK. OK. We read it or we saw it in some document, and we're just trying to recall. We've gone through thousands of documents. We thought some directive in there, a comment made that you would just—don't worry about the final product; just do the environmental testing.

Mr. MACKAY. I don't believe so. But we can check.

I would say, though, that if you have exhaustive environmental testing, and you have a food safety plan in place and you are following good manufacturing processes, that the probability of your having a problem in the final food is mitigated significantly.

But—I would have to check that, Congressman, but I don't believe that would be the case.

Mr. STUPAK. If you would get back, I would like to see that. Because it bothers us if that is the situation because I think we've got all responsibility through the whole chain, from the grower all the way down to the person who puts it on the shelves, to make sure that food is safe.

Mr. MACKAY. Just to add to your comment, to your question, I think everyone has a responsibility in the chain. And I think the more comprehensive that we can make the food safety system in the U.S. through the supplier, through the manufacturer principally, the more likely we are to really improve the food safety in the U.S., which I believe is already very good. But it clearly can be improved.

Mr. STUPAK. Well, from where we sit, this is what, our fifteenth hearing in about 18 months or so, just on food safety alone. That's not even counting the drug hearings we've had on drug safety. And I guess we're just bothered by no standards and everyone's doing it a little differently.

We have three witnesses here who are all trying to do the right thing. They have three different systems going. We need to have some uniformity so we know what to look for.

And these audits, on tab 23 there, where Sam Lightsey gets notice in December there is going to be an audit. It will take place on March 23–24. I have got time to clean up the dead rodents; I have time to clean up the flies, the beetles, rodent droppings, the feathers, whatever it may be. And that must come to an end.

I guess we're looking forward. I know you all gave us suggestions on what to do. We appreciate it. We appreciate you all trying to help out in this matter and for your testimony today. And I want to thank you for being here and thanks for putting up with our questions and answering the questions under oath to the best of your ability.

And we look forward to some further answers. All members will have 10 days to submit additional questions for the record, so don't be surprised if we contact you and ask for additional information.

And with that, I—that concludes our hearing. I want to thank once again all the witnesses, the members for their active participation. Thank you.

Mr. KANAN. Thank you.

[Whereupon, at 1:13 p.m., the subcommittee was adjourned.]

[Material submitted for inclusion in the record follows:]

STATEMENT OF CONGRESSMAN JOHN SULLIVAN

Committee on Energy and Commerce
Oversight and Investigations Subcommittee hearing
The Salmonella Outbreak: the Role of Industry in Protecting the Nation's Food Supply
March 19, 2009

I would like to thank Chairman Stupak and Ranking Member Walden for holding this hearing this morning. I am pleased to be a part of this important discussion on food safety as we examine the actions and obligations of manufacturers and retailers that purchased tainted peanut butter products from the Peanut Corporation of America.

Unfortunately, the salmonella outbreak has hit my state of Oklahoma. According to the Oklahoma Department of Health four adolescents contracted salmonella due to the tainted peanut butter. One of those adolescents was from Rogers County which borders my district. Fortunately, they all recovered but this serves as a reminder that we must take every precaution necessary to keep our food supply safe.

In late 2008, the CDC indentified an outbreak of salmonella affecting 677 people in 45 states and Canada with the recent outbreak perhaps contributing to 9 deaths. This is an issue that affects each and every one of us, our friends and our families. It is clear that the food companies and the FDA have a shared responsibility in keeping our food supply safe and secure and I look forward to industry's recommendations on how to do that in light of the recent salmonella outbreak.

Thank you in advance to our panels before us today. I look forward to hearing the testimonies of our witnesses and I yield back the balance of my time.